Perkins Coie

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VIA CM/ECF

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Jarrett B. Perlow
Circuit Executive and Clerk of Court
United States Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, DC 2043

Re: Citation of Supplemental Authority in *Google LLC v. Sonos, Inc.*, No. 2024-1097

Dear Mr. Perlow:

I write to advise the Court and opposing counsel of additional authorities on which Google will rely at oral argument. These authorities undermine Sonos's suggestions (Grey Br. 14-23) that a patentee can satisfy the written-description requirement using (a) a patchwork of disclosures that at most suggested or implied a critical claim limitation without clearly describing it, or (b) internal evidence that may show when an invention was privately conceived but not when the invention was publicly disclosed in a patent application.

In *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), the Court reaffirmed that a patent application must "*clearly* allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Id.* at 1351 (emphasis added). Mere hints or suggestions in a specification are not enough, as "novel aspects of the invention must be disclosed and not left to inference." *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1380 (Fed. Cir. 2002). *Ariad* also stressed that internal conception documents are immaterial to the written-description inquiry because "the hallmark of written description is disclosure" within the "four corners of the specification." 598 F.3d at 1351.

In *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336 (Fed. Cir. 2013), the Court emphasized that patentees and their experts may not "work[ ] backward from a knowledge of the claims" and "derive written description support from an amalgam of disclosures plucked selectively from [an] application," as Sonos has done here. *Id.* at 1349 (affirming JMOL of no adequate written description);

see also Biogen Int'l GmbH v. Mylan Pharms. Inc., 18 F.4th 1333 (Fed. Cir. 2021) (similarly affirming invalidity ruling where patentee relied on scattered passages in its specification). *Novozymes* also reaffirmed the longstanding principle that disclosing a genus (here zone scenes) does not disclose a particular species of that genus (here *overlapping* zone scenes) unless "blaze marks" in the specification single out that particular species. 723 F.3d at 1346-47 (citing *In re Ruschig*, 379 F.2d 990, 993-94 (CCPA 1967)). Sonos's 2006 and 2007 applications contained no such blaze marks.

Respectfully submitted,

/s/Dan L. Bagatell

Dan L. Bagatell

Counsel for Appellee Google LLC

Attachments (cited cases)

cc: all counsel of record (by CM/ECF)

598 F.3d 1336
United States Court of Appeals, Federal Circuit.

ARIAD PHARMACEUTICALS, INC., Massachusetts Institute of Technology, The Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College,
Plaintiffs–Appellees,
v.
ELI LILLY AND COMPANY,
Defendant–Appellant.

No. 2008–1248
|
March 22, 2010.

Synopsis
Background: Owners of patent claiming methods comprising the single step of reducing Nuclear Factor Kappa B (NF-kB) activity in eukaryotic cells brought infringement action against competitor. After a jury found infringement, and concluded that the asserted claims were not invalid for anticipation, lack of enablement, or lack of written description, the United States District Court for the District of Massachusetts, Rya W. Zobel, J., 529 F.Supp.2d 106, denied competitor's motion for judgment as a matter of law (JMOL), and a final judgment was entered, 2007 WL 2712087. Competitor appealed. The United States Court of Appeals for the Federal Circuit, 560 F.3d 1366, affirmed in part and reversed in part, and patentees petitioned for rehearing en banc.

Holdings: The Court of Appeals, en banc, Lourie, Circuit Judge, held that:

[1] statute requiring that patent specification contain a written description of the invention contained a written description requirement separate from enablement, and

[2] patent was invalid for failure to provide adequate written description.

Reversed in part and affirmed in part.

Newman, Circuit Judge, wrote separately, expressing additional views.

Gajarsa, Circuit Judge, filed concurring opinion.

Rader, Circuit Judge, filed opinion dissenting-in-part and concurring-in-part in which Linn, Circuit Judge, joined.

Linn, Circuit Judge, filed opinion dissenting-in-part and concurring-in-part in which Rader, Circuit Judge, joined.

Procedural Posture(s): On Appeal; Motion for Judgment as a Matter of Law (JMOL)/Directed Verdict.

West Headnotes (8)

[1] **Patents** Written Description Requirement
Patents Enablement Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k908Enablement Requirement
291k908(1)In general
(Formerly 291k99)

Statute governing content of specification contains a written description requirement separate from enablement; statute contains two separate description requirements: a written description of the invention, and of the manner and process of making and using the invention. 35 U.S.C.A. § 112.

304 Cases that cite this headnote

[2] **Patents** Written Description Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)

Written description requirement for a patent specification applies to all claims and requires that patent specification objectively demonstrate that the applicant actually invented—was in possession of—the claimed subject matter; written description requirement contains no basis for applying a different standard to amended versus original claims. 35 U.S.C.A. § 112.

436 Cases that cite this headnote

[3] **Patents** Written Description Requirement
Patents Possession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention
(Formerly 291k99)

Test for sufficiency of written description of a patent specification is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date; level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. 35 U.S.C.A. § 112.

500 Cases that cite this headnote

[4] **Patents** Written Description Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)

Written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. 35 U.S.C.A. § 112.

169 Cases that cite this headnote

[5] **Patents** Written Description Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)

While written description requirement does not demand any particular form of disclosure or require that patent specification recite the claimed invention in haec verba, a description that merely renders the invention obvious does not satisfy the requirement. 35 U.S.C.A. § 112.

111 Cases that cite this headnote

[6] **Patents** Particular products or processes

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(6)Particular products or processes
(Formerly 291k99)

Owners of patent claiming methods comprising the single step of reducing Nuclear Factor Kappa B (NF-kB) activity in eukaryotic cells failed to provide adequate written description of the claims by hypothesizing three classes of molecules potentially capable of reducing

NF-kB activity, and therefore the claims were invalid, where the patent disclosed no working or even prophetic examples of the molecules prophesized to be capable of reducing NF-kB activity. 35 U.S.C.A. § 112.

6 Cases that cite this headnote

[7] **Patents** Specification and description; enablement

291Patents
291VIIPatent Infringement
291VII(C)Actions
291VII(C)7Appellate Review
291k1965Scope, Standard, and Extent of Review
291k1970Particular Matters
291k1970(9)Patent Applications and Proceedings
291k1970(11)Specification and description; enablement
(Formerly 291k324.55(3.1), 291k314(5))

A determination that a patent is invalid for failure to meet the written description requirement is a question of fact, and Court of Appeals reviews a jury's determinations of facts relating to compliance with the written description requirement for substantial evidence. 35 U.S.C.A. § 112.

199 Cases that cite this headnote

[8] **Patents** In general; utility

291Patents
291XPatents Enumerated
291k2091In general; utility
(Formerly 291k328(2))

US Patent 6,410,516. Invalid.

4 Cases that cite this headnote

Attorneys and Law Firms

***1337** John M. Whealan, of Silver Spring, MD, argued for plaintiffs-appellees. With him on the brief were James W. Dabney, Stephen S. Rabinowitz, and Randy C. Eisensmith, Fried Frank Harris Shriver & Jacobson LLP, of New York, NY, and John F. Duffy, of Washington, DC. Of counsel were Leora Ben–Ami, Patricia A. Carson, Christopher T, Jagoe, Sr., Matthew McFarlane, and Howard S. Suh, Kaye Scholer LLP, of New York, NY.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Reston, VA, argued for defendant-appellant. With him on the brief were Robert D. Bajefsky, David S. Forman, Howard W. Levine, Laura P. Masurovsky, and Jennifer A. Johnson, of Washington, DC, and Jennifer S. Swan, of Palo Alto, CA. Of counsel on the brief were Paul R. Cantrell, Gilbert T. Voy, and Alexander Wilson, Eli Lilly and Company, of Indianapolis, IN. Of counsel was Sanya Sukduang, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC.

***1338** Mark R. Freeman, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for amicus curiae United States. With him on the brief were Ann Ravel, Acting Assistant Attorney General, and Scott R. McIntosh, Attorney. Of counsel on the brief were James A. Toupin, General Counsel, and Raymond T. Chen, Solicitor, United States Patent and Trademark Office, of Arlington, VA.

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R. Carl Moy, William Mitchell College of Law, of St. Paul, MN, for amicus curiae William Mitchell College of Law, Intellectual Property Institute. With him on the brief was Jay A. Erstling.

William F. Lee, Wilmer Cutler Pickering Hale and Dorr LLP, of Boston, MA, for amicus curiae Abbott Laboratories. With him on the brief were William G. McElwain, Randolph D. Moss, Amy K. Wigmore, and Thomas G. Saunders of Washington, DC. Of counsel on the brief were Eric P. Martin and Peter N. Witty, Abbott Laboratories, of Abbott Park, IL.

Nancy J. Linck, Rothwell, Figg, Ernst & Manbeck, P.C., of Washington, DC, for amicus curiae Monsanto Company. With her on the brief were Minaksi Bhatt and Martha Cassidy. Of counsel on the brief was Dennis R. Hoerner, Monsanto Company, of St. Louis, MO.

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Richard A. Samp, Washington Legal Foundation, of Washington, DC, for amicus curiae Washington Legal Foundation. With him on the brief was Daniel J. Popeo.

Lloyd R. Day, Jr., Howrey LLP, of East Palo Alto, CA, for amicus curiae Amgen Inc. With him on the brief was Linda A. Sasaki–Baxley. Of counsel on the brief were Stuart L. Watt, Wendy A. Whiteford, Monique L. Cordray, and Gail A. Katz, Amgen Inc., of Thousand Oaks, CA.

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Joshua D. Sarnoff, Glushko–Samuelson Intellectual Property Law Clinic, Washington College of Law, American University, of Washington, DC, for amicus curiae Public Patent Foundation.

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, RADER, BRYSON, GAJARSA, LINN, DYK,

PROST, and MOORE, Circuit Judges.

Opinion for the court filed by Circuit Judge LOURIE, in which Chief Judge MICHEL and Circuit Judges NEWMAN, MAYER, BRYSON, GAJARSA, DYK, PROST, and MOORE join. Additional views filed by Circuit Judge NEWMAN. Concurring opinion filed by Circuit Judge GAJARSA. Dissenting-in-part, concurring-in-part opinion filed by Circuit Judge RADER, in which Circuit Judge LINN joins. Dissenting-in-part, concurring-in-part opinion filed by Circuit Judge LINN, in which Circuit Judge RADER joins.

Opinion

***1340** LOURIE, Circuit Judge.

Ariad Pharmaceuticals, Inc., Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research, and the President and Fellows of Harvard College (collectively, "Ariad") brought suit against Eli Lilly & Company ("Lilly") in the United States District Court for the District of Massachusetts, alleging infringement of U.S. Patent 6,410,516 ("the '516 patent"). After trial, at which a jury found infringement, but found none of the asserted claims invalid, a panel of this court reversed the district court's denial of Lilly's motion for judgment as a matter of law ("JMOL") and held the asserted claims invalid for lack of written description. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366 (Fed.Cir.2009).

Ariad petitioned for rehearing *en banc,* challenging this court's interpretation of 35 U.S.C. § 112, first paragraph, as containing a separate written description requirement. Because of the importance of the issue, we granted Ariad's petition and directed the parties to address whether § 112, first paragraph, contains a written description requirement separate from the enablement requirement and, if so, the scope and purpose of that requirement. We now reaffirm that § 112, first paragraph, contains a written description requirement separate from enablement, and we again reverse the district court's denial of JMOL and hold the asserted claims of the '516 patent invalid for failure to meet the statutory written description requirement.

BACKGROUND

The '516 patent relates to the regulation of gene expression by the transcription factor NF-êB. The inventors of the '516 patent were the first to identify NF-êB and to uncover the mechanism by which NF-êB activates gene expression underlying the body's immune responses to infection. The inventors discovered that NF-êB normally exists in cells as an inactive complex with a protein inhibitor, named "IêB" ("Inhibitor of kappa B"), and is activated by extracellular stimuli, such as bacterial-produced lipopolysaccha rides, through a series of biochemical reactions that release it from IêB. Once free of its inhibitor, NF-êB travels into the cell nucleus where it binds to and activates the transcription of genes containing a NF-êB recognition site. The activated genes (*e.g.,* certain cytokines), in turn help the body to counteract the extracellular assault. The production of cytokines can, however, be harmful in excess. Thus the inventors recognized that artificially interfering with NF-êB activity could reduce the harmful symptoms of certain diseases, and they filed a patent application on April 21, 1989, disclosing their discoveries and claiming methods for regulating cellular responses to external stimuli by reducing NF-êB activity in a cell.

Ariad brought suit against Lilly on June 25, 2002, the day the '516 patent issued. Ariad alleged infringement of claims 80, 95, 144, and 145 by Lilly's Evista® and Xigris® pharmaceutical products. The asserted claims, rewritten to include the claims from which they depend, are as follows:

> 80. [A method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF-êB-mediated intracellular signaling, the method comprising altering NF-êB activity in the cells such that NF-êB-mediated effects of external influences are modified, wherein NF-êB activity in the cell is reduced] wherein reducing NF-êB activity comprises reducing binding of NF-êB to NF-êB recognition sites on genes which are transcriptionally regulated by NF-êB.
>
> ***1341** 95. [A method for reducing, in eukaryotic cells, the level of expression of genes which are activated by extracellular influences which induce NF-êBmediated intracellular signaling, the method comprising reducing NF-êB activity in the cells such that expression of said genes is reduced], carried out on human cells.
>
> 144. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-êB activity in the cells so as to reduce bacterial

> lipopolysaccharide-induced expression of said cytokines in the cells] wherein reducing NF-êB activity comprises reducing binding of NF-êB to NF-êB recognition sites on genes which are transcriptionally regulated by NF-êB.
>
> 145. [A method for reducing bacterial lipopolysaccharide-induced expression of cytokines in mammalian cells, which method comprises reducing NF-êB activity in the cells so as to reduce bacterial lipopolysaccharide-induced expression of said cytokines in the cells], carried out on human cells.

The claims are thus genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF-êB to NF-êB recognition sites. Furthermore, the claims, although amended during prosecution, use language that corresponds to language present in the priority application. Specifically, the asserted claims recite methods of reducing NF-êB activity, and more specifically reducing binding of NF-êB to NF-êB recognition sites, in cells in response to external influences like bacterial lipopolysaccha rides. The specification filed on April 21, 1989, similarly recites the desired goal of reducing NF-êB activity and binding to NF-êB recognition sites in cells in response to such external influences. *See '* 516 patent col.3 l.59–col.4 l.19; col.31 l.65–col.32 l.11; *see also id.* at col.2 ll.54–59. The specification also hypothesizes three types of molecules with the potential to reduce NF-êB activity in cells: decoy, dominantly interfering, and specific inhibitor molecules. *Id.* at col.37 l.43–col.38 l.22.

In April 2006, the district court held a fourteen-day jury trial on the issues of infringement and validity. The jury rendered a special verdict finding infringement of claims 80 and 95 with respect to Evista® and claims 144 and 145 with respect to Xigris®. The jury also found that the asserted claims were not invalid for anticipation, lack of enablement, or lack of written description. The court denied without opinion Lilly's motions for JMOL and, in the alternative, a new trial. In August 2006, the court conducted a four-day bench trial on Lilly's additional defenses of unpatentable subject matter, inequitable conduct, and prosecution laches, ruling in favor of Ariad on all three issues. *Ariad Pharms., Inc. v. Eli Lilly & Co.,* 529 F.Supp.2d 106 (D.Mass.2007).

Lilly timely appealed to this court, and on April 3, 2009, a panel affirmed in part and reversed in part. *Ariad,* 560 F.3d at 1369. The panel upheld the district court's finding of no inequitable conduct, *id.* at 1380, but reversed the jury's verdict on written description, holding the asserted claims invalid for lack of an adequate written description as required by 35 U.S.C. § 112, first paragraph, *id.* at 1376. Ariad petitioned for rehearing *en banc,* challenging the existence of a written description requirement in § 112, first paragraph, separate from the enablement requirement. Although not a new question, *see In re Barker,* 559 F.2d 588, 591–93 (CCPA 1977), its prominence has increased in recent years, *see Lizardtech, Inc. v. Earth Res. Mapping, Inc.,* 433 F.3d 1373 (Fed.Cir.2005) (denying rehearing *en banc* on the question whether a separate written description requirement exists in § 112, first paragraph); ***1342** *Univ. of Rochester v. G.D. Searle & Co., Inc.,* 375 F.3d 1303 (Fed.Cir.2004) (same); *Enzo Biochem, Inc. v. Gen–Probe Inc.,* 323 F.3d 956, 970 (Fed.Cir.2002) (same). In light of the controversy concerning the distinctness and proper role of the written description requirement, we granted Ariad's petition, vacating the prior panel opinion and directing the parties to brief two questions:

(1) Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?

(2) If a separate written description requirement is set forth in the statute, what is the scope and purpose of that requirement?

In addition to the parties' briefs, the court received twenty-five amicus briefs. Of those, seventeen were filed in support of Lilly, one was filed in support of Ariad, and seven were filed in support of neither party. The majority, including a brief filed by the United States, were filed in support of this court's current written description doctrine. The court heard oral arguments on December 7, 2009.

DISCUSSION

I.

Although the parties differ in their answers to the court's questions, their positions converge more than they first appear. Ariad, in answering the court's first question, argues that § 112, first paragraph, does *not* contain a written description requirement separate from enablement. Yet, in response to this court's second question on the scope and purpose of a written description requirement, Ariad argues that the statute contains two description requirements: "Properly interpreted, the statute requires the specification to describe (i) what the invention is, and (ii) how to make and use it." Appellee

Br. 1; *see also id.* at 43 ("[T]he written description requirement of § 112, ¶ 1 requires, first, that the specification describe (identify) what the invention is and, second, that the specification teach how to make and use the invention."). Ariad reconciles this apparent contradiction by arguing that the legal sufficiency of its two-prong description requirement is judged by whether it enables one of skill in the art to make and use the claimed invention. Thus, according to Ariad, in order to enable the invention, the specification must first identify "*what* the invention is, for otherwise it fails to inform a person of skill in the art what to make and use." *Id.* at 30. Yet Ariad argues that this first step of "identifying" the invention applies only in the context of priority (*i.e.,* claims amended during prosecution; priority under 35 U.S.C. §§ 119, 120; and interferences) because original claims "constitute their own description." *Id.* at 44.

Lilly, in contrast, answers the court's first question in the affirmative, arguing that two hundred years of precedent support the existence of a statutory written description requirement separate from enablement. Thus, Lilly argues that the statute requires, first, a written description of the invention and, second, a written description of how to make and use the invention so as to enable one of skill in the art to make and use it. Finally, Lilly asserts that this separate written description requirement applies to all claims—both original and amended—to ensure that inventors have actually invented the subject matter claimed.

Thus, although the parties take diametrically opposed positions on the existence of a written description requirement separate from enablement, both agree that the specification must contain a written description of the invention to establish what the invention is. The dispute, therefore, centers on the standard to be applied and whether it applies to original claim language.

***1343** A.

As in any case involving statutory interpretation, we begin with the language of the statute itself. *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.,* 447 U.S. 102, 108, 100 S.Ct. 2051, 64 L.Ed.2d 766 (1980). Section 112, first paragraph, reads as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

According to Ariad, a plain reading of the statute reveals two components: a written description (i) of the invention, and (ii) of the manner and process of making and using it. Yet those two components, goes Ariad's argument, must be judged by the final prepositional phrase; both written descriptions must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same." Specifically, Ariad parses the statute as follows:

> The specification shall contain
>
> [A] a written description
>
> [i] of the invention, and
>
> [ii] of the manner and process of making and using it,
>
> [B] in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same ...

Ariad argues that its interpretation best follows the rule of English grammar that prepositional phrases (here, "of the invention," "of the manner and process of making and using it," and "in such full, clear, concise, and exact terms") modify another word in the sentence (here, "written description"), and that it does not inexplicably ignore the comma after "making and using it" or sever the "description of the invention" from the requirement that it be in "full, clear, concise, and exact terms," leaving the description without a legal standard.

Ariad also argues that earlier versions of the Patent Act support its interpretation. Specifically, Ariad contends that the first Patent Act, adopted in 1790, and its immediate successor, adopted in 1793, required a written description of the invention that accomplished two purposes: (i) to distinguish the invention from the prior art, and (ii) to enable a person skilled in the art to make and use the invention.[1] Ariad then asserts that when

Congress assigned the function of defining the invention to the claims in 1836, Congress amended the written description requirement so that it served a single purpose: enablement.[2]

[1] Section 3 of the 1793 Patent Act provided, in relevant part: "[E]very inventor, before he can receive a patent shall ... deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same."

[2] Section 6 of the 1836 Patent Act provided, in relevant part: "[B]efore any inventor shall receive a patent for any such new invention or discovery, he shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same."

***1344** Lilly disagrees, arguing that § 112, first paragraph, contains three separate requirements. Specifically, Lilly parses the statute as follows:

> (1) "The specification shall contain a written description of the invention, *and* "
>
> (2) "The specification shall contain a written description ... of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, *and* "
>
> (3) "The specification ... shall set forth the best mode contemplated by the inventor of carrying out the invention."

Lilly argues that Ariad's construction ignores a long line of judicial precedent interpreting the statute's predecessors to contain a separate written description requirement, an interpretation Congress adopted by reenacting the current language of § 112, first paragraph, without significant amendment.

[1] We agree with Lilly and read the statute to give effect to its language that the specification "shall contain a written description of the invention" and hold that § 112, first paragraph, contains two separate description requirements: a "written description [i] of the invention, *and* [ii] of the manner and process of making and using [the invention"]. 35 U.S.C. § 112, ¶ 1 (emphasis added). On this point, we do not read Ariad's position to be in disagreement as Ariad concedes the existence of a written description requirement. *See* Appellee Br. 2 ("Under a plain reading of the statute, a patent specification ... must contain a description (i) of the invention, and (ii) of the manner and process of making and using it."). Instead Ariad contends that the written description requirement exists, not for its own sake as an independent statutory requirement, but only to identify the invention that must comply with the enablement requirement.

But, unlike Ariad, we see nothing in the statute's language or grammar that unambiguously dictates that the adequacy of the "written description of the invention" must be determined solely by whether that description identifies the invention so as to enable one of skill in the art to make and use it. The prepositional phrase "in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same" modifies only "the written description ... of the manner and process of making and using [the invention]," as Lilly argues, without violating the rules of grammar. That the adequacy of the description of the manner and process of *making* and *using* the invention is judged by whether that description enables one skilled in the art to *make* and *use* the same follows from the parallelism of the language.

While Ariad agrees there is a requirement to describe the invention, a few amici appear to suggest that the only description requirement is a requirement to describe enablement. If Congress had intended enablement to be the sole description requirement of § 112, first paragraph, the statute would have been written differently. Specifically, Congress could have written the statute to read, "The specification shall contain a written description of the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same," or "The specification shall contain a written description of the manner and process of making and using the invention, in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same." Under the amicis' construction a portion of the statute—either ***1345** "and of the manner and process of making and using it" or "[a written

description] of the invention"—becomes surplusage, violating the rule of statutory construction that Congress does not use unnecessary words. *See United States v. Menasche,* 348 U.S. 528, 538–39, 75 S.Ct. 513, 99 L.Ed. 615 (1955) ("It is our duty 'to give effect, if possible, to every clause and word of a statute.' ") (quoting *Montclair v. Ramsdell,* 107 U.S. 147, 152, 2 S.Ct. 391, 27 L.Ed. 431 (1883)).

Furthermore, since 1793, the Patent Act has expressly stated that an applicant must provide a written description of the invention, and after the 1836 Act added the requirement for claims, the Supreme Court applied this description requirement separate from enablement. *See infra* Section I.B. Congress recodified this language in the 1952 Act, and nothing in the legislative history indicates that Congress intended to rid the Act of this requirement. On the contrary, "Congress is presumed to be aware of a[ ] ... judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change." *Forest Grove Sch. Dist. v. T.A.,* 557 U.S. 230, 129 S.Ct. 2484, 2492, 174 L.Ed.2d 168 (2009) (quoting *Lorillard v. Pons,* 434 U.S. 575, 580, 98 S.Ct. 866, 55 L.Ed.2d 40 (1978)).

Finally, a separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention. It is part of the *quid pro quo* of a patent; one describes an invention, and, if the law's other requirements are met, one obtains a patent. The specification must then, of course, describe how to make and use the invention (*i.e.,* enable it), but that is a different task. A description of the claimed invention allows the United States Patent and Trademark Office ("PTO") to examine applications effectively; courts to understand the invention, determine compliance with the statute, and to construe the claims; and the public to understand and improve upon the invention and to avoid the claimed boundaries of the patentee's exclusive rights.

B.

Ariad argues that Supreme Court precedent comports with its reading of the statute and provides no support for a written description requirement separate from enablement. Specifically, Ariad asserts that in *Evans v. Eaton,* 20 U.S. (7 Wheat.) 356, 433–34, 5 L.Ed. 472 (1822), the Supreme Court recognized just two requirements under § 3 of the 1793 Act, the requirements "to enable" the invention and "to distinguish" it from all things previously known. And, goes Ariad's argument, since the 1836 Act, which removed the latter language and added the requirement for claims, the Court has consistently held that a patent applicant need fulfill but a single "written description" requirement, the measure of which is enablement.

Lilly disagrees and reads Evans as acknowledging a written description requirement separate from enablement. Lilly further contends that the Court has continually confirmed the existence of a separate written description requirement, including in *O'Reilly v. Morse,* 56 U.S. (15 How.) 62, 14 L.Ed. 601 (1853) under the 1836 Act; *Schriber–Schroth Co. v. Cleveland Trust Co.,* 305 U.S. 47, 59 S.Ct. 8, 83 L.Ed. 34 (1938), under the 1870 Act; and more recently in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 736, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002).

Like Lilly, we also read Supreme Court precedent as recognizing a written description requirement separate from an enablement requirement even after the introduction of claims. Specifically, in *Schriber–Schroth,* the Court held that a patent directed to pistons for a gas engine with ***1346** "extremely rigid" webs did not adequately describe amended claims that recited flexible webs under the then-in-force version of § 112, first paragraph.[3] 305 U.S. at 56–57, 59 S.Ct. 8. The Court ascribed two purposes to this portion of the statute, only the first of which involved enablement:

> [1] to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and [2] to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be

[3] Section 26 of the 1870 Patent Act provided, in relevant part: "[B]efore any inventor or discoverer shall receive a patent for his invention or discovery, he shall ... file in the patent office a written description of [his invention or discovery], and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same."

> safely used or manufactured without a license and which may not.

Id. at 57, 59 S.Ct. 8. The Court then concluded that even if the original specification enabled the use of a flexible web, the claim could derive no benefit from it because "that was not the invention which [the patentee] *described* by his references to an extremely rigid web." *Id.* at 58–59, 59 S.Ct. 8 (emphasis added); *see also MacKay Radio & Tel. Co. v. Radio Corp. of Am.,* 306 U.S. 86, 98–102, 59 S.Ct. 427, 83 L.Ed. 506 (1939) (holding invalid claims amended to include structures "not within the invention described in the application" even though the variations were small). Although the Court did not expressly state that it was applying a description of the invention requirement separate from enablement, that is exactly what the Court did.[4]

[4] *Morse,* decided under the 1836 Act, can also be interpreted as involving a separate written description inquiry. 56 U.S. (15 How.) 62, 14 L.Ed. 601. The patent at issue contained eight claims, only seven of which recited the specific instrumentalities of the telegraph developed by Morse. The eighth claim, in contrast, claimed every conceivable way of printing intelligible characters at a distance by the use of an electric or galvanic current. *Id.* at 112. The Court rejected the latter claim as too broad because Morse claimed "an exclusive right to use a manner and process which he has not *described* and indeed had not invented, and therefore could not *describe* when he obtained his patent." *Id.* at 113 (emphasis added). Such a rejection implies a distinct requirement for a description of the invention. Yet, in reaching its conclusion, the Court also detailed how the claim covered inventions not yet made, indicating the additional failure of the description to enable such a broad claim. *See id.* at 113–14.

Further, both before and after *Schriber–Schroth,* the Court has stated that the statute serves a purpose other than enablement. In *Gill v. Wells,* 89 U.S. (22 Wall.) 1, 22 L.Ed. 699 (1874), the Court held invalid a reissue patent for claiming a combination not described in the original application, but the Court also emphasized the need for all patents to meet the "three great ends" of § 26, only one of which was enablement. Specifically, the Court stated:

> (1) That the government may know what they have granted and what will become public property when the term of the monopoly expires. (2.) That licensed persons desiring to practice the invention may know, during the term, how to make, construct, and use the invention.(3.) That other inventors may know what part of the field of invention is unoccupied.

Id. at 25–26. Finally, most recently in *Festo*, the Court recited three requirements for § 112, first paragraph, and noted ***1347** a written description requirement separate from the others:

> [T]he patent application must *describe, enable, and set forth the best mode* of carrying out the invention. These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public. What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue. The patent also should not issue if the other requirements of § 112 are not satisfied....

535 U.S. at 736, 122 S.Ct. 1831 (emphasis added) (internal citations omitted). As a subordinate federal court, we may not so easily dismiss such statements as dicta but are bound to follow them. *See Stone Container Corp. v. United States,* 229 F.3d 1345, 1349–50 (Fed.Cir.2000). While Ariad points to statements in other cases that support its view, Appellee Br. 18–19, not one disavows the existence of a separate written description requirement.

A separate written description requirement also does not conflict with the function of the claims. 35 U.S.C. § 112, ¶ 2. Claims define the subject matter that, after examination, has been found to meet the statutory requirements for a patent. *See In re Vamco Mach. & Tool, Inc.,* 752 F.2d 1564, 1577 n. 5 (Fed.Cir.1985). Their

principal function, therefore, is to provide notice of the boundaries of the right to exclude and to define limits; it is not to describe the invention, although their original language contributes to the description and in certain cases satisfies it. Claims define and circumscribe, the written description discloses and teaches.

C.

In addition to the statutory language and Supreme Court precedent supporting the existence of a written description requirement separate from enablement, *stare decisis* impels us to uphold it now. Ariad acknowledges that this has been the law for over forty years, *see* Appellee Br. 24, and to change course now would disrupt the settled expectations of the inventing community, which has relied on it in drafting and prosecuting patents, concluding licensing agreements, and rendering validity and infringement opinions. As the Supreme Court stated in admonishing this court, we "must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo,* 535 U.S. at 739, 122 S.Ct. 1831; *see also Watson v. United States,* 552 U.S. 74, 82, 128 S.Ct. 579, 169 L.Ed.2d 472 (2007) ("A difference of opinion within the Court ... does not keep the door open for another try at statutory construction, where *stare decisis* has special force [since] the legislative power is implicated, and Congress remains free to alter what we have done." (internal quotations omitted)). If the law of written description is to be changed, contrary to sound policy and the uniform holdings of this court, the settled expectations of the inventing and investing communities, and PTO practice, such a decision would require good reason and would rest with Congress.

D.

Ariad next argues that an incorrect reading of *In re Ruschig,* 54 C.C.P.A. 1551, 379 F.2d 990 (1967), by our predecessor court, the Court of Customs and Patent Appeals ("CCPA"), and then by this court, created the first written description requirement separate from enablement. Yet Ariad also asserts, in response to Lilly's argument that *In re Moore,* 33 C.C.P.A. 1083, 155 F.2d 379 (1946); *In re Sus,* 49 C.C.P.A. 1301, 306 F.2d 494 (1962); and *Jepson v. Coleman,* 50 C.C.P.A. 1051, 314 F.2d 533 (1963), applied a separate written description requirement pre- ***1348** *Ruschig,* that those cases "merely tested whether the specification *identified* the same invention that was defined by later-added or amended claims—which is an aspect of enablement—and did not interpret § 112, ¶ 1 as containing an independent description-possession requirement." Appellee Br. 22–23. Thus, according to Ariad, a written description of the invention is required but is not separate from enablement because it identifies the invention that must be enabled, and this, in Ariad's view, differs from first requiring the invention to be described and then separately requiring it to be enabled.

We view this argument as a distinction without a practical difference insofar as both approaches require a written description of the invention in the specification. In either case the analysis compares the claims with the invention disclosed in the specification, and if the claimed invention does not appear in the specification, both Ariad and Lilly agree that the claim—whether in *Schriber–Schroth* or *Ruschig*—fails regardless whether one of skill in the art could make or use the claimed invention. *Ruschig* involved a claim amended during prosecution to recite a specific chemical compound, chlorpropamide. 379 F.2d at 991. The specification as filed disclosed a genus encompassing about "half a million possible compounds," but it did not disclose chlorpropamide specifically. *Id.* at 993. The CCPA affirmed the PTO's rejection of the compound claim because the specification provided no guides or "blaze marks" to single out chlorpropamide from all the other compounds, and thus did not support the later-added claim. *Id.* at 994–95. The court also rejected the argument that one of skill in the art would be enabled to make chlorpropamide as "beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented," which, the court held, it did not. *Id.* at 995–96.

According to Ariad, the court properly rejected Ruschig's claim based on enablement because the specification did not identify the later-claimed compound, leaving the skilled artisan with no guide to select that compound from the myriad of other compounds encompassed by the broad disclosure. According to Lilly, the court properly rejected the claim under a written description requirement separate from enablement because the specification did not disclose the later-claimed compound to one of skill in the art as something the inventors actually invented out of the myriad of other compounds encompassed by the broad disclosure. Again, this difference amounts to little more than semantics as the parties agree that the court properly affirmed the rejection because the original application did not disclose the specific claimed invention, chlorpropamide, even if one of skill in the art could, based on the disclosure with respect to related compounds,

make and use it.

Ariad also argues that the court properly rejected Ruschig's claim as violating 35 U.S.C. § 132's prohibition on "new matter." But § 132 is an examiner's instruction, and unlike § 282 of the Patent Act, which makes the failure to comply with § 112 a defense to infringement, § 132 provides no statutory penalty for a breach. Express statutory invalidity defenses carry more weight than examiner's instructions, and prohibiting adding new matter to the claims has properly been held enforceable under § 112, first paragraph. *See In re Rasmussen,* 650 F.2d 1212, 1214–15 (CCPA 1981). Regardless, one can fail to meet the requirements of the statute in more than one manner, and the prohibition on new matter does not negate the need to provide a written description of one's invention.

***1349** E.

[2] In contrast to amended claims, the parties have more divergent views on the application of a written description requirement to original claims. Ariad argues that *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559 (Fed.Cir.1997), extended the requirement beyond its proper role of policing priority as part of enablement and transformed it into a heightened and unpredictable general disclosure requirement in place of enablement. Rather, Ariad argues, the requirement to describe what the invention is does not apply to original claims because original claims, as part of the original disclosure, constitute their own written description of the invention. Thus, according to Ariad, as long as the claim language appears *in ipsis verbis* in the specification as filed, the applicant has satisfied the requirement to provide a written description of the invention.

Lilly responds that the written description requirement applies to all claims and requires that the specification objectively demonstrate that the applicant actually invented—was in possession of—the claimed subject matter. Lilly argues that § 112 contains no basis for applying a different standard to amended versus original claims and that applying a separate written description requirement to original claims keeps inventors from claiming beyond their inventions and thus encourages innovation in new technological areas by preserving patent protection for actual inventions.

Again we agree with Lilly. If it is correct to read § 112, first paragraph, as containing a requirement to provide a separate written description of the invention, as we hold here, Ariad provides no principled basis for restricting that requirement to establishing priority. Certainly nothing in the language of § 112 supports such a restriction; the statute does not say "The specification shall contain a written description of the invention *for purposes of determining priority.*" And although the issue arises primarily in cases involving priority, Congress has not so limited the statute, and neither will we.

Furthermore, while it is true that original claims are part of the original specification, *In re Gardner,* 480 F.2d 879, 879 (CCPA 1973), that truism fails to address the question whether original claim language necessarily discloses the subject matter that it claims. Ariad believes so, arguing that original claims identify whatever they state, *e.g.,* a perpetual motion machine, leaving only the question whether the applicant has enabled anyone to make and use such an invention. Oral Argument 37:26–38:00. We disagree that this is always the case. Although many original claims will satisfy the written description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.

Recognizing this, we held in *Eli Lilly* that an adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries. ***1350** 119 F.3d at 1568. The patent at issue in *Eli Lilly* claimed a broad genus of cDNAs purporting to encode many different insulin molecules, and we held that its generic claim language to "vertebrate insulin cDNA" or "mammalian insulin cDNA" failed to describe the claimed genus because it did not distinguish the genus from other materials in any way except by function, *i.e.,* by what the genes do, and thus provided "only a definition of a useful result rather than a definition of what achieves that result." *Id.*

We held that a sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or

structural features common to the members of the genus so that one of skill in the art can "visualize or recognize" the members of the genus. *Id.* at 1568–69. We explained that an adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials. *Id.* at 1568 (quoting *Fiers v. Revel,* 984 F.2d 1164, 1171 (Fed.Cir.1993)). We have also held that functional claim language can meet the written description requirement when the art has established a correlation between structure and function. *See Enzo,* 323 F.3d at 964 (quoting 66 Fed.Reg. 1099 (Jan. 5, 2001)). But merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.

In fact, this case similarly illustrates the problem of generic claims. The claims here recite methods encompassing a genus of materials achieving a stated useful result, i.e., reducing NF-êB binding to NF-êB recognition sites in response to external influences. But the specification does not disclose a variety of species that accomplish the result. *See Eli Lilly,* 119 F.3d at 1568 ("The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention."). Thus, as indicated *infra,* that specification fails to meet the written description requirement by describing only a generic invention that it purports to claim.

We also specifically addressed and rejected Ariad's argument regarding original claims in *Fiers,* 984 F.2d at 1170, and again in *Enzo,* 323 F.3d at 968. In *Fiers,* we rejected the argument that "only similar language in the specification *or original claim* is necessary to satisfy the written description requirement." 984 F.2d at 1170 (emphasis added). Rather, we held that original claim language to "a DNA coding for interferon activity" failed to provide an adequate written description as it amounted to no more than a "wish" or "plan" for obtaining the claimed DNA rather than a description of the DNA itself. *Id.* at 1170–71. That *Fiers* applied § 112, first paragraph, during an interference is irrelevant for, as we stated above, the statute contains no basis for ignoring the description requirement outside of this context. And again in *Enzo* we held that generic claim language appearing *in ipsis verbis* in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed. 323 F.3d at 968. We concluded that "[a] claim does not become more descriptive by its repetition, or its longevity." *Id.* at 969.

Ariad argues that *Eli Lilly* constituted a change in the law, imposing new requirements on biotechnology inventions. We disagree. Applying the written description requirement outside of the priority ***1351** context in our 1997 *Eli Lilly* decision merely faithfully applied the statute, consistent with Supreme Court precedent and our case law dating back at least to our predecessor court's *Ruschig* decision. Neither the statute nor legal precedent limits the written description requirement to cases of priority or distinguishes between original and amended claims. The application of the written description requirement to original language was raised in *Fiers, Eli Lilly*, and *Enzo,* and is raised again by the parties here. Once again we reject Ariad's argument and hold that generic language in the application as filed does not automatically satisfy the written description requirement.

F.

[3] Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a "fairly uniform standard," which we now affirm. *Vas–Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1562–63 (Fed.Cir.1991). Specifically, the description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Id.* at 1563 (citing *In re Gosteli,* 872 F.2d 1008, 1012 (Fed.Cir.1989)). In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *Id.* (quoting *Ralston Purina Co. v. Far–Mar–Co, Inc.,* 772 F.2d 1570, 1575 (Fed.Cir.1985)); *see also In re Kaslow,* 707 F.2d 1366, 1375 (Fed.Cir.1983).

The term "possession," however, has never been very enlightening. It implies that as long as one can produce records documenting a written description of a claimed invention, one can show possession. But the hallmark of written description is disclosure. Thus, "possession as shown in the disclosure" is a more complete formulation. Yet whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

This inquiry, as we have long held, is a question of fact. *Ralston Purina,* 772 F.2d at 1575. Thus, we have recognized that determining whether a patent complies with the written description requirement will necessarily vary depending on the context. *Capon v. Eshhar,* 418 F.3d 1349, 1357–58 (Fed.Cir.2005). Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *Id.* For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Id.* at 1359.

The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges. Thus, we do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied. Nor do we set out any bright-line rules governing, for example, the number of species that must be disclosed to describe a genus claim, as this number necessarily changes with each invention, and it changes with progress in a field. *Compare Eli Lilly,* 119 F.3d at 1567 (holding an ***1352** amino acid sequence did not describe the DNA sequence encoding it), *with In re Wallach,* 378 F.3d 1330, 1334 (Fed.Cir.2004) (discussing how it is now a "routine matter" to convert an amino acid sequence into all the DNA sequences that can encode it). Thus, whatever inconsistencies may appear to some to exist in the application of the law, those inconsistencies rest not with the legal standard but with the different facts and arguments presented to the courts.

[4] [5] There are, however, a few broad principles that hold true across all cases. We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko–Gunter Falkner v. Inglis,* 448 F.3d 1357, 1366–67 (Fed.Cir.2006). Conversely, we have repeatedly stated that actual "possession" or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, *Carnegie Mellon Univ. v. Hoffmann–La Roche Inc.,* 541 F.3d 1115, 1122 (Fed.Cir.2008), or that the specification recite the claimed invention *in haec verba,* a description that merely renders the invention obvious does not satisfy the requirement, *Lockwood v. Am. Airlines,* 107 F.3d 1565, 1571–72 (Fed.Cir.1997).

We also reject the characterization, cited by Ariad, of the court's written description doctrine as a "super enablement" standard for chemical and biotechnology inventions. The doctrine never created a heightened requirement to provide a nucleotide-by-nucleotide recitation of the entire genus of claimed genetic material; it has always expressly permitted the disclosure of structural features common to the members of the genus. *Eli Lilly,* 119 F.3d at 1569; *see also Invitrogen Corp. v. Clontech Labs., Inc.,* 429 F.3d 1052, 1073 (Fed.Cir.2005) (holding the written description requirement satisfied by a representative number of sequences of the claimed genus of enzymes). It also has not just been applied to chemical and biological inventions. *See LizardTech, Inc. v. Earth Res. Mapping, Inc.,* 424 F.3d 1336, 1343–47 (Fed.Cir.2005).

Perhaps there is little difference in some fields between describing an invention and enabling one to make and use it, but that is not always true of certain inventions, including chemical and chemical-like inventions. Thus, although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described. For example, a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent. *See In re DiLeone,* 58 C.C.P.A. 925, 436 F.2d 1404, 1405 n. 1 (1971) ("[C]onsider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described.").

The written description requirement also ensures that when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function—a problem that is ***1353** particularly acute in the biological arts.[5] *See Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1, "Written Description" Requirement,* 66 Fed.Reg. 1099, 1105–1106 (Jan. 5, 2001). This situation arose not only in *Eli Lilly* but again in *University of Rochester v. G.D. Searle & Co., Inc.,* 358 F.3d 916 (Fed.Cir.2004). In *Rochester,* we held invalid claims directed to a method of selectively

inhibiting the COX–2 enzyme by administering a non-steroidal compound that selectively inhibits the COX–2 enzyme. *Id.* at 918. We reasoned that because the specification did not describe any specific compound capable of performing the claimed method and the skilled artisan would not be able to identify any such compound based on the specification's function description, the specification did not provide an adequate written description of the claimed invention. *Id.* at 927–28. Such claims merely recite a description of the problem to be solved while claiming all solutions to it and, as in Eli *Lilly* and Ariad's claims, cover any compound later actually invented and determined to fall within the claim's functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention.

[5] The record does not reflect how often the PTO rejects claims as enabled but not described, but the government believes the number to be high. Oral Argument at 23:17–23:53. At least one example has made it to this court in recent years, *In re Alonso*, in which the PTO found claims to a method of treating a tumor by administering an effective amount of an antibody that recognizes the tumor enabled but, as we affirmed, not adequately described. 545 F.3d 1015, 1021–22, 1022 n. 6. (Fed.Cir.2008).

Ariad complains that the doctrine disadvantages universities to the extent that basic research cannot be patented. But the patent law has always been directed to the "useful Arts," U.S. Const. art. I, § 8, cl. 8, meaning inventions with a practical use, *see Brenner v. Manson,* 383 U.S. 519, 532–36, 86 S.Ct. 1033, 16 L.Ed.2d 69 (1966). Much university research relates to basic research, including research into scientific principles and mechanisms of action, *see, e.g., Rochester,* 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Id.* at 930 n. 10 (quoting *Brenner,* 383 U.S. at 536, 86 S.Ct. 1033). Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public.

That research hypotheses do not qualify for patent protection possibly results in some loss of incentive, although Ariad presents no evidence of any discernable impact on the pace of innovation or the number of patents obtained by universities. But claims to research plans also impose costs on downstream research, discouraging later invention. The goal is to get the right balance, and the written description doctrine does so by giving the incentive to actual invention and not "attempt[s] to preempt the future before it has arrived." *Fiers,* 984 F.2d at 1171. As this court has repeatedly stated, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's ***1354** contribution to the field of art as described in the patent specification." *Rochester,* 358 F.3d at 920 (quoting *Reiffin v. Microsoft Corp.,* 214 F.3d 1342, 1345 (Fed.Cir.2000)). It is part of the *quid pro quo* of the patent grant and ensures that the public receives a meaningful disclosure in exchange for being excluded from practicing an invention for a period of time. *Enzo,* 323 F.3d at 970.

II.

Because we reaffirm our written description doctrine, we see no reason to deviate from the panel's application of that requirement to the facts of this case. As such, we adopt that analysis, as follows, as the decision of the *en banc* court.

A.

We review the denial of Lilly's motion for JMOL without deference. *CytoLogix Corp. v. Ventana Med. Sys., Inc.,* 424 F.3d 1168, 1172 (Fed.Cir.2005) (applying First Circuit law). Under First Circuit law, JMOL is warranted pursuant to Fed.R.Civ.P. 50(a)(1) where "there is no legally sufficient evidentiary basis for a reasonable jury to find" for the non-moving party. *Guilloty Perez v. Pierluisi,* 339 F.3d 43, 50 (1st Cir.2003) (quotations omitted). "A patent is presumed to be valid, and this presumption only can be overcome by clear and convincing evidence to the contrary." *Enzo,* 424 F.3d at 1281 (citing *WMS Gaming Inc. v. Int'l Game Tech.,* 184 F.3d 1339, 1355 (Fed.Cir.1999)); *see* 35 U.S.C. § 282.

Ariad explains that developing the subject matter of the '516 patent "required years of hard work, great skill, and extraordinary creativity—so much so that the inventors

first needed to discover, give names to, and describe previously unknown cellular components as a necessary predicate for their inventions." Lilly offered the undisputed expert testimony of David Latchman that the field of the invention was particularly unpredictable. Thus, this invention was made in a new and unpredictable field where the existing knowledge and prior art was scant. *See Capon,* 418 F.3d at 1359.

B.

[6] Ariad claims methods comprising the single step of reducing NF-êB activity. Lilly argues that the asserted claims are not supported by a written description because the specification of the '516 patent fails to adequately disclose how the claimed reduction of NF-êB activity is achieved. The parties agree that the specification of the '516 patent hypothesizes three classes of molecules potentially capable of reducing NF-êB activity: specific inhibitors, dominantly interfering molecules, and decoy molecules. Lilly contends that this disclosure amounts to little more than a research plan, and does not satisfy the patentee's *quid pro quo* as described in *Rochester.* Ariad responds that Lilly's arguments fail as a matter of law because Ariad did not actually claim the molecules. According to Ariad, because there is no term in the asserted claims that corresponds to the molecules, it is entitled to claim the methods without describing the molecules. Ariad's legal assertion, however, is flawed.

In *Rochester,* as discussed above, we held very similar method claims invalid for lack of written description. 358 F.3d at 918–19 (holding the patent invalid because "Rochester did not present any evidence that the ordinarily skilled artisan would be able to identify any compound based on [the specification's] vague functional description"); *see also Fiers,* 984 F.2d at 1170–71 (holding a claim to a genus of DNA molecules not supported by written description of a method for obtaining the molecules); *cf. Eli Lilly,* 119 F.3d at 1567–68 (holding claims to a broad genus ***1355** of genetic material invalid because the specification disclosed only one particular species). Ariad attempts to categorically distinguish *Rochester, Fiers*, and *Eli Lilly,* because in those cases, the claims explicitly included the non-described compositions. For example, in *Rochester,* the method claims recited a broad type of compound that we held was inadequately described in the specification of the patent:

> 1. A method for selectively inhibiting PGHS–2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS–2 gene product to a human host in need of such treatment.

Id. at 918 (emphasis added). Ariad's attempt to distinguish these cases is unavailing. Regardless whether the asserted claims recite a compound, Ariad still must describe some way of performing the claimed methods, and Ariad admits that the specification suggests only the use of the three classes of molecules to achieve NF-êB reduction. Thus, to satisfy the written description requirement for the asserted claims, the specification must demonstrate that Ariad possessed the claimed methods by sufficiently disclosing molecules capable of reducing NF-êB activity so as to "satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon,* 418 F.3d at 1357.

C.

[7] Alternatively, Ariad argues that the specification of the '516 patent and the expert testimony of Tom Kadesch provided the jury with substantial evidence of adequate written description of the claimed methods. "A determination that a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact, and we review a jury's determinations of facts relating to compliance with the written description requirement for substantial evidence." *PIN/NIP, Inc. v. Platte Chem. Co.,* 304 F.3d, 1235, 1243 (Fed.Cir.2002) (citing *Vas–Cath,* 935 F.2d at 1563).

Much of Ariad's written description evidence, however, is legally irrelevant to the question of whether the disclosure of the '516 patent conveys to those skilled in the art that the inventors were in possession of the claimed generic invention on April 21, 1989—the effective filing date of the '516 patent. The parties disputed the effective filing date of the '516 patent, and in a detailed and well-crafted special verdict form, the jury was asked to choose between the two possible dates: April 21, 1989, and November 13, 1991. The jury chose 1989 and neither party appealed that determination. Presumably because of

uncertainty over the priority date, much of Ariad's evidence was actually directed to the later date. Because written description is determined as of the filing date—April 21, 1989, in this case—evidence of what one of ordinary skill in the art knew in 1990 or 1991 cannot provide substantial evidence to the jury that the asserted claims were supported by adequate written description. *See Vas–Cath,* 935 F.2d at 1563–64 (holding that a written description analysis occurs "as of the filing date sought").

In accordance with *Rochester,* the '516 patent must adequately describe the claimed methods for reducing NF-êB activity, including adequate description of the molecules that Ariad admits are necessary to perform the methods. The specification of the '516 patent hypothesizes three classes of molecules potentially capable of reducing NF-êB activity: specific inhibitors, dominantly interfering molecules, and decoy molecules. We review the specification's disclosure of each in turn to determine whether there is substantial ***1356** evidence to support the jury's verdict that the written description evidenced that the inventor possessed the claimed invention.

Specific inhibitors are molecules that are "able to block (reduce or eliminate) NF-êB binding" to DNA in the nucleus. '516 patent col.37 ll.44–45. The only example of a specific inhibitor given in the specification is I-êB, a naturally occurring molecule whose function is to hold NF-êB in an inactive state until the cell receives certain external influences. *Id.* at col.37 ll.48–49. Nearly all of Ariad's evidence regarding the disclosure of I-êB relies upon figure 43. Ariad's expert, Dr. Kadesch, testified that figure 43 discloses the sequence of DNA that encodes I-êB and relied on this disclosure with regard to his opinion that the written description requirement was satisfied by disclosure of specific inhibitor molecules. *See* Trial Tr. 53; 57–58; 60; 78–85, Apr. 27, 2006. But as Ariad admits, figure 43 was not disclosed until 1991. Because figure 43 was not in the 1989 application, neither it nor Dr. Kadesch's testimony regarding it can offer substantial evidence for the jury determination. *See Vas–Cath,* 935 F.2d at 1563–64. The only other testimony of Dr. Kadesch with regard to I-êB was that it existed in 1989 and that one of ordinary skill could through experimentation isolate natural I-êB. *See* Trial Tr. at 62–85. In the context of this invention, a vague functional description and an invitation for further research does not constitute written disclosure of a specific inhibitor.[6] *See Eli Lilly,* 119 F.3d at 1566 (holding that written description requires more than a "mere wish or plan for obtaining the claimed chemical invention"); *see also id.* at 1567 ("[A] description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention."). And it certainly does not constitute written disclosure of a method for reducing NF-êB activity using I-êB.

[6] Moreover, the district court found, in the context of its inequitable conduct ruling, that figure 43 is both incorrect and incomplete. *Ariad Pharms.,* 529 F.Supp.2d at 123–25 (finding those errors material). That the inventors of the '516 patent, among the most skilled artisans in their field in the world at this time, failed to correctly disclose the structure of I-êB even two years after the application was filed is a strong sign that one of skill in the art could not be expected to provide this knowledge in 1989.

Dominantly interfering molecules are "a truncated form of the NF-êB molecule." '516 patent col.38 l.11. The truncation would "retain[ ] the DNA binding domain, but lack[ ] the RNA polymerase activating domain." *Id.* at col.38 ll.13–14. As such, the dominantly interfering molecule "would recognize and bind to the NF–KB binding site [on nuclear DNA], however, the binding would be unproductive." *Id.* at col.38 ll.15–17. In other words, the dominantly interfering molecules would block natural NF-êB from inducing the expression of its target genes. The specification provides no example molecules of this class. Moreover, the specification acknowledges that dominantly interfering molecules can work only "*if* the DNA binding domain and the DNA polymerase domain of NF-êB are spatially distinct in the molecule." *Id.* at col.38 ll.9–10 (emphasis added). The jury also heard Dr. Kadesch's testimony that "it is a fair representation" that "the '516 patent itself doesn't disclose in its text that the DNA binding domain and the RNA preliminary activating domain of NF-êB are, in fact, separable or spatially distinct." Considering that the inventors of the '516 patent discovered NF-êB, if they did not know whether the two domains are distinct, one of ordinary skill in the art was at best equally ignorant. Perhaps one of ordinary skill could discover this information, but this does not alter our conclusion that the ***1357** description of the dominantly interfering molecules "just represents a wish, or arguably a plan" for future research. *Fiers,* 984 F.2d at 1171; *see Eli Lilly,* 119 F.3d at 1567 (rendering obvious is insufficient for written description). Nor is it sufficient, as Ariad argues, that "skilled workers actually practiced this teaching soon after the 1989 application was filed." *See Vas–Cath,* 935 F.2d at 1563–64 (holding that a written description analysis occurs "as of the filing date sought").

Decoy molecules are "designed to mimic a region of the

gene whose expression would normally be induced by NF-êB. In this case, NF-êB would bind the decoy, and thus, not be available to bind its natural target." ′ 516 patent col.37 ll.51–54. Like the other two classes of molecules, decoy molecules are presented hypothetically, but unlike the other two classes of molecules, the specification proposes example structures for decoy molecules. *Id.* at col.37 tbl.2. As Dr. Kadesch explained, decoy molecules are DNA oligonucleotides, and because the specification discloses specific example sequences, there is little doubt that the specification adequately described the actual molecules to one of ordinary skill in the art. Yet this does not answer the question whether the specification adequately describes using those molecules to reduce NF-êB activity. The full extent of the specification's disclosure of a method that reduces NF-êB activity using decoy molecules is that NF-êB "would bind the decoy" and thereby, "negative regulation can be effected." *Id.* at col.37 ll.50–54. Prophetic examples are routinely used in the chemical arts, and they certainly can be sufficient to satisfy the written description requirement. But this disclosure is not so much an "example" as it is a mere mention of a desired outcome. As Dr. Latchman pointed out, there is no descriptive link between the table of decoy molecules and reducing NF–KB activity.

Ariad also relies upon "[a] 1990 publication in evidence [that] reported using decoy molecules to reduce NF-êB activity" which was discussed by Dr. Kadesch. Appellee Br. 25–26. Again, because the priority date was determined to be 1989, the disclosure in a later publication cannot, as a matter of law, establish that the inventor in this case possessed using decoy molecules to reduce NF-êB when the patent application was filed in 1989. Dr. Kadesch's reliance on this evidence as support for his opinion is likewise erroneous.[7]

[7] Dr. Kadesch testified that the scientists who conducted the decoy molecule study published in November 1990 would likely have mastered their technique prior to the filing of the ′516 patent application in April 1989. Perhaps so, but this fact is not in evidence, and even if it were true, one research group does not necessarily represent the knowledge of one of ordinary skill in the art without further testimony to support that contention.

We reviewed all other portions of Dr. Kadesch's testimony that Ariad contends provided the jury with substantial evidence relating to each of the three classes of molecules, and we deem them insufficient as a matter of law.[8] Indeed, most of the testimony cited by Ariad was irrelevant to the question whether the inventors were in possession of the claimed invention as of the 1989 priority date. The ′516 patent discloses no working or even prophetic ***1358** examples of methods that reduce NF-êB activity, and no completed syntheses of any of the molecules prophesized to be capable of reducing NF-êB activity. The state of the art at the time of filing was primitive and uncertain, leaving Ariad with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure. *See Capon,* 418 F.3d at 1358 ("It is well-recognized that in the unpredictable fields of science, it is appropriate to recognize the variability in the science in determining the scope of the coverage to which the inventor is entitled.").

[8] Dr. Kadesch certainly offered a general conclusion that he thought the inventors were in possession of the claimed invention in 1989. This conclusory testimony, as shown *infra,* is devoid of any factual content upon which the jury could have relied when considering the specification of the ′516 patent, and therefore cannot constitute substantial evidence. Besides, possession of an invention must be shown by written description in the patent application, and that was not shown here. *See Rochester,* 358 F.3d at 926 ("After all, it is in the patent specification where the written description requirement must be met.").

Whatever thin thread of support a jury might find in the decoy-molecule hypothetical simply cannot bear the weight of the vast scope of these generic claims. *See LizardTech,* 424 F.3d at 1345 (holding that "[a]fter reading the patent, a person of skill in the art would not understand" the patentee to have invented a generic method where the patent only disclosed one embodiment of it); *Reiffin,* 214 F.3d at 1345–46 (noting that the "scope of the right to exclude" must not "overreach the scope of the inventor's contribution to the field of art as described in the patent specification"); *Fiers,* 984 F.2d at 1171 ("Claiming all DNA[s] that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived."); *cf. Carnegie Mellon,* 541 F.3d at 1126 (holding that the narrow description of the *E. coli polA* gene did not adequately support a broad claim to the gene from any bacterial source). Here, the specification at best describes decoy molecule structures and hypothesizes with no accompanying description that they could be used to reduce NF-êB activity. Yet the asserted claims are far broader. We therefore conclude that the jury lacked substantial evidence for its verdict that the asserted claims were supported by adequate written description, and thus hold the asserted claims

invalid.

CONCLUSION

For the foregoing reasons, we hold that the asserted claims of the '516 patent are invalid for lack of written description, and we do not address the other validity issues that were before the panel. We also reinstate Part II of the panel decision reported at 560 F.3d 1366 (Fed.Cir.2009), affirming the district court's finding of no inequitable conduct. The judgment below is

REVERSED IN PART AND *AFFIRMED IN PART*

NEWMAN, Circuit Judge, additional views.

I join the court's opinion. However, I write separately because the real issue of this case is too important to be submerged in rhetoric. The issue was recognized by Ariad, who complained that the written description requirement "has severe adverse consequences for research universities" because it prevents the patenting of "the type of discoveries that universities make," that is, it prevents the patenting of basic scientific research. Ariad Br. on Rehearing En Banc at 38–39. This question is squarely joined in this case, for the subject matter is indeed basic research, which was taken to the patent system before its practical application was demonstrated. In the district court, this aspect was discussed in terms of Section 101. The panel preferred Section 112; and the en banc court has now been diverted into a scholarly debate about the punctuation in the first paragraph of Section 112.

As the facts reach us, a previously unknown protein, called NF-kB (Nuclear Factor kappaB), was discovered and found to mediate certain intracellular signaling. The scientists/inventors postulated that reducing NF-kB activity can reduce the ***1359** symptoms of certain diseases, and they identified three general methods of achieving that reduction, *viz.,* by using decoy cells, dominantly interfering molecules, and specific inhibitor molecules. None of these methods was tried, although they are discussed in the patent specification, and the postulated physiological result was not shown. However, the record states that other scientists have successfully conducted further experiments in this field, building on this scientific achievement.

Ariad argues that the patentees made a basic discovery, and are not required to demonstrate its application in order to patent their "pioneering" achievement. Indeed, pioneering inventions can receive broad patents, when shown to have broad scope. The court deems the absence of any specific example of the postulated method of reducing symptoms to be a failure in the description of the invention. The dissenters appear to deem the inclusion of general methods whereby this result could be achieved, to suffice for patentability of the basic scientific concept. These are close, fact-dependent questions, raising many issues, as the large number of amicus curiae briefs attest.

In my view, the overriding policy of patent systems requires both written description and enablement, and it is less critical to decide which statutory clause applies in a particular case, than to assure that both requirements are met. This has been the practice since the first Patent Act, as the opinions and amici have explored. How this is achieved varies with many factors, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue." *Capon v. Eshhar,* 418 F.3d 1349, 1359 (Fed.Cir.2005). Although the content varies, the threshold in all cases requires a transition from theory to practice, from basic science to its application, from research plan to demonstrated utility.

The written description is the way by which the scientific/technologic information embodied in patented inventions is disseminated to the public, for addition to the body of knowledge and for use in further understanding and advance. *See id.* at 1357 ("The written description requirement thus satisfies the policy premises of the law, whereby the inventor's technical/scientific advance is added to the body of knowledge, as consideration for the grant of patent exclusivity."). This accords with long-standing principles, as in the classical case of *O'Reilly v. Morse,* 56 U.S. (15 How.) 62, 14 L.Ed. 601 (1853), where the Court approved Samuel Morse's claims based on the system of current boosters that achieved his long-distance communication called the telegraph, but denied his claims for this use of an electric current "however developed." *Id.* at 113. As the court debates the relationship between "written description" and "enablement," let us not lose sight of the purpose of Section 112.

Basic scientific principles are not the subject matter of patents, while their application is the focus of this law of commercial incentive. The role of the patent system is to encourage and enable the practical applications of scientific advances, through investment and commerce. Although Ariad points out that "basic patents" of broad scope are well recognized, several amici point out that in no case has an invention of basic science been patented

with not even one embodiment demonstrating its application and illustrating its breadth. Lilly points out that the specification herein demonstrates none of the three methods that are suggested for possible use to reduce NF-kB activity in cells.

The practical utility on which commercial value is based is the realm of the patent grant; and in securing this exclusionary ***1360** right, the patentee is obliged to describe and to enable subject matter commensurate with the scope of the exclusionary right. This is not a question of grammatical nuance of the placement of commas in Section 112; it is a question of the principle and policy of patent systems. The court's opinion implements these precepts.

GAJARSA, Circuit Judge, concurring.

I join the opinion of the court, but write separately to explain my reasons for doing so. Whether there is a free standing written description requirement pursuant to § 112, ¶ 1 is a matter of statutory interpretation as the majority correctly notes. Maj. Op. at 1342–45. In my judgment, the text of § 112, ¶ 1 is a model of legislative ambiguity. The interpretation of the statute, therefore, is one over which reasonable people can disagree, and indeed, reasonable people have so disagreed for the better part of a decade. *See, e.g., Univ. of Rochester v. G.D. Searle & Co.,* 375 F.3d 1303 (Fed.Cir.2004) (denial of rehearing en banc); *Enzo Biochem, Inc. v. Gen–Probe Inc.,* 323 F.3d 956 (Fed.Cir.2002) (denial of rehearing en banc). While not entirely free from doubt, the majority's interpretation of § 112, ¶ 1 is reasonable, and for the need to provide some clarity to this otherwise conflicting area of our law, I concur with the majority's opinion that the statute may be interpreted to set forth an independent written description requirement.

I disagree, however, with those who view an independent written description requirement as a necessity of patent law. This court and the various amici curiae have spent considerable time and resources addressing whether § 112, ¶ 1 provides a distinct written description requirement wholly separate from enablement. Contrary to the representations of the Patent Office and the opinions of members of this court, I do not believe that this issue has a significant, practical impact. *See* Government Br. at 19 (claiming written description serves an "indispensable role in the administration of the patent system"); *Moba, B.V. v. Diamond Automation, Inc.,* 325 F.3d 1306, 1322 (Rader, J., concurring) ("By making written description a free-standing disclosure doctrine, this court produces numerous unintended and deleterious consequences."). Empirical evidence demonstrates that outside the priority context the written description doctrine seldom serves as a separate vehicle for invalidating claims. *See, e.g.,* Dennis Crouch, *An Empirical Study of the Role of the Written Description Requirement in Patent Prosecution* 12 (Univ. of Mo. Sch. Of Law Legal Studies Research Paper No.2010–06, 2000), *available at* http://ssrn.com/abstract=1554949 (analyzing 2858 Board of Patent Appeals and Interference patent opinions decided between January and June 2009 and finding "none of the outcomes of those decisions would have been impacted by a hypothetical change that eliminated the written description requirement so long as new matter rejections were still allowed under the same standard available today"); Christopher Holman, *Is Lilly Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and its Progeny in the Courts and PTO,* 17 Alb. L.J. Sci. & Tech. 1, 26–78 (2007) (analyzing Federal Circuit, district court, and BPAI cases since *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559 (Fed.Cir.1997), and finding only a small number of cases that invalidated a claim for failure to satisfy the written description requirement).[1]

[1] More specifically, Holman finds that (1) written description challenges to a patent's validity rarely arise, and (2) when they do occur, very few patents have been invalidated, whether by the Federal Circuit, district courts or the BPAI. According to Holman, over a nine-year period, the Federal Circuit rejected written description-based challenges on six occasions, while it upheld such challenges in only four cases. During the same period of time and excluding those decisions addressed by the Federal Circuit, district courts rejected written description challenges on ten occasions, and upheld them once. Finally, the BPAI rejected written description challenges on twenty-two occasions, while upholding them only nine times. *Id.* at 26–78.
Furthermore, Holman discusses each of the cases before the courts and the BPAI where a challenge under the written description requirement was upheld and argues that in most cases the patent would have also been invalid for lack of enablement or that the court or BPAI substantially blurred the line between enablement and written description. *Id.* at 78–79.

***1361** The empirical evidence confirms my belief that written description serves little practical purpose as an

independent invalidity device and better serves the goals of the Patent Act when confined to the priority context. As a matter of statutory interpretation, however, we cannot limit the written description only to priority cases, but Congress could establish such a limit by statute. Section 112, ¶ 1's enablement requirement is a more than adequate vehicle for invalidating claims that are broader than their disclosure. *See J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc.*, 534 U.S. 124, 142, 122 S.Ct. 593, 151 L.Ed.2d 508 (2001) (identifying an enabling disclosure as the quid pro quo of the patent monopoly); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed.Cir.2009) ("To meet the enablement requirement, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation."). Confining written description to the priority context would provide greater clarity to district courts and practitioners, both of whom are currently left to trudge through a thicket of written description jurisprudence that provides no conclusive answers and encourages a shotgun approach to litigation. Yet, this thicket is the result of our best efforts to construe an ambiguous statute; only Congress wields the machete to clear it.

Accordingly, because the majority's opinion provides a reasonable interpretation of a less than clear statute, I join the opinion.

RADER, Circuit Judge, with whom LINN, Circuit Judge, joins, dissenting-in-part and concurring-in-part.

The Constitution of the United States gives Congress, not the courts, the power to promote the progress of the useful arts by securing exclusive rights to inventors for limited times. Art. I, § 8, cl. 8. Yet this court proclaims itself the body responsible for achieving the "right balance" between upstream and downstream innovation. Ante at 1353. The Patent Act, however, has already established the balance by requiring that a patent application contain "a written description of the invention, and of the manner and process of making and using it, *in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same.*" 35 U.S.C. § 112, ¶ 1 (emphasis added). In rejecting that statutory balance in favor of an undefined "written description" doctrine, this court ignores the problems of standardless decision making and serious conflicts with other areas of patent law. Because the Patent Act already supplies a better test, I respectfully dissent.

I.

The frailties of this court's "written description" doctrine have been exhaustively documented in previous opinions. *See,* ***1362** *e.g., Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 976 (Fed.Cir.2002) (Rader, J., dissenting from denial of rehearing en banc); *id.* at 987 (Linn, J., dissenting from denial of rehearing en banc); *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1322 (Fed.Cir.2003) (Rader, J., concurring); *id.* at 1327 (Bryson, J., concurring); *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303, 1307 (Fed.Cir.2004) (Rader, J., dissenting from denial of rehearing en banc); *id.* at 1325 (Linn, J., dissenting from denial of rehearing en banc); *Lizardtech, Inc. v. Earth Res. Mapping, Inc.*, 433 F.3d 1373, 1376 (Fed.Cir.2006) (Rader, J., dissenting from denial of rehearing en banc); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1380 (Fed.Cir.2009) (Linn, J., concurring). These earlier writings document the embarrassingly thin (perhaps even mistaken) justifications for the minting of this new description doctrine in 1997 and the extensive academic criticism of this product of judicial imagination. For present purposes I will only recount those frailties of this court's relatively recent justifications for a doctrine of its own making.

First and foremost, the separate written description requirement that the court petrifies today has no statutory support. As noted, § 112, first paragraph, reads as follows:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

This language, while cumbersome, is unambiguous. It says that the written descriptions of the invention and of the manner and process of making and using the invention

are both judged by whether they are in such full, clear, concise, and exact terms as to enable a person skilled in the art to make and use the invention. The reason for a description doctrine is clear: to ensure that the inventor fully discloses the invention in exchange for an exclusive right. The test for the adequacy of the specification that describes the invention is also clear: Is the description sufficient to enable a person of ordinary skill in the art to make and use the claimed invention? Nowhere does the paragraph require that the inventor satisfy some quixotic possession requirement.

This court, however, calves the "written description of the invention" language out of its context in the rest of the paragraph. In this court's strained reading, the prepositional phrases that follow apply only to a "written description ... of the manner and process of making and using" the invention, not to a "written description of the invention." The practical effect of the court's interpretation is that the written description of the invention contained in the specification need not be full. It need not be clear. It need not be concise. It need not be exact. *But see Phillips v. AWH Corp.,* 415 F.3d 1303, 1316 (Fed.Cir.2005) (en banc) ("The close kinship between the written description and the claims is enforced by the statutory requirement that the specification describe *the claimed invention* in 'full, clear, concise, and exact terms.' ") (emphasis added). And, of course, it need not enable. Instead, it must satisfy a vague possession notion.

To support its reading of the statute, the court relies on a new doctrine of statutory interpretation that it calls "parallelism." *Ante* at 1344. Before today, parallelism would have been simply disfavored under the maxim that the law does not use redundant ***1363** language, a maxim that has actually been used by courts before. (Indeed, even the court uses this maxim when it fits its purpose, *see ante* at 1344–45.) If Congress had intended enablement to test only the sufficiency of the written description of the manner and process of making and using the invention, then it would have simply required "a written description ... of the manner and process of making and using it in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to *do so.*" Note also that the comma after "it" in the statute as written is meaningless under the court's interpretation.

Moreover, if "parallelism" is indeed the right test, then it conflicts with the court's separate argument that the written description of the invention test has been separate from the enablement test since the 1793 Act. A close look at Section 3 of the 1793 Act reveals that the "parallelism" there connects the enablement clause to both written description requirements:

> [E]very inventor, before he can receive a patent shall ... deliver a written description *of his invention,* and of the manner of *using,* or process of *compounding* the same, in such full, clear and exact terms ... to enable any person skilled ... to *make, compound,* and use, the same.

Act of Feb. 27, 1793, 1 Stat. 318, 321–22, ch. 11, § 3 (emphasis added).

In reality, the court simply sidesteps the conflict between its position and the language of the statute by suggesting that Supreme Court precedent has settled this issue. *Ante* at 1344–45. Of course, that is a question for the Supreme Court to answer, but reading the statute as it is written is in fact fully consistent with cases like *Schriber–Schroth Co. v. Cleveland Trust Co.,* 305 U.S. 47, 59 S.Ct. 8, 83 L.Ed. 34 (1938).

Specifically, the description doctrine under a correct reading of the statute shows that a specification satisfies the "written description of the invention" requirement when it tells a person of skill in the art what the invention is. In other words, a proper reading of the statutory description requirement recognizes that the enablement requirement identifies the invention and tells a person of ordinary skill *what* to make and use. Of course, the original claims must always, by statute, "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." § 112, ¶ 2. *Schriber–Schroth,* as the court acknowledges, dealt with amended claims, as did *MacKay Radio & Tel. Co. v. Radio Corp. of Am.,* 306 U.S. 86, 59 S.Ct. 427, 83 L.Ed. 506 (1939), and *Gill v. Wells,* 89 U.S. (22 Wall.) 1, 22 L.Ed. 699 (1874). These cases stand only for the unremarkable proposition that an applicant cannot add new matter to an original disclosure. Thus Supreme Court precedent is fully consistent with the logical reading of the statute and impeaches this court's *ultra vires* imposition of a new written description requirement for original claims, an imposition that first arose in *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559, 1566–69 (Fed.Cir.1997).

At this point, this dissent could once again document, as in *Enzo,* that every case before this court's fabrication in

1997 actually applied the "written description" doctrine to police priority. Before 1982, this court's predecessor referred to this doctrine as a new matter prohibition with respect to claims. *See In re Rasmussen,* 650 F.2d 1212, 1214 (CCPA 1981) ("The proper basis for rejection of a *claim* amended to recite elements thought to be without support in the original disclosure ... is § 112, first paragraph, not § 132.... [The latter section] is properly employed as a basis for objection to amendments to the abstract, specifications, or drawings ....") (emphasis added). In *Eli Lilly,* this court tragically did not even ***1364** realize that it was breaking new ground. It was not until *Enzo* that the court really became aware of its own activism. 323 F.3d at 971 (Lourie, J., concurring) ("It is said that applying the written description requirement outside of the priority context was novel until several years ago. Maybe so, maybe not; certainly such a holding was not precluded by statute or precedent. New interpretations of old statutes in light of new fact situations occur all the time."). In sum, to its own surprise, the court learned in *Enzo* that it had applied the written description doctrine according to its broad title when in fact the doctrine had never policed description in general but only new matter abuses.

With *Enzo,* rather than admit error, this court began to thrash about to try and locate support for its new creation. Sadly this court cannot find any Supreme Court case that supports its new creation. This court attempts to twist some words in *O'Reilly v. Morse* to support its new conception. *See* 56 U.S. (15 How.) 62, 120–21, 14 L.Ed. 601 (1853) ("[A person] can lawfully claim only what he has invented and described, and if he claims more his patent is void."). That case, however, did not ask the Court to address whether an enabling description would have been sufficient (which is probably why the court relegates its description of *Morse* to a footnote, *see ante* at 1364 n. 4). And this court clearly overstates the language of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* where the Supreme Court discussed passingly a non-exhaustive list of requirements found in § 112 as a whole, not simply the first paragraph. *See* 535 U.S. 722, 736, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002).[*]

[*] The court's reliance on *Festo, ante* at 1346–47, is all the more perplexing because the Supreme Court in that case hardly purported to resolve the present question of massive consequence for all of patent law. *See El Paso Co. v. United States,* 694 F.2d 703, 711 (Fed.Cir.1982) (stating in the context of pertinent dicta from a Supreme court opinion: "Usually ... one seeking for valid precedents will pay more attention to what courts actually do with the case before them, than to dicta pronouncing rules textually extending beyond the facts of that case to other cases undreamt of by the deciding tribunal."). This court's need to point to dicta to support its conclusion merely establishes the point that the Supreme Court has yet to decide the issue.

As a kicker for its statutory interpretation, the court draws on the "*quid pro quo* of a patent." *Ante* at 1345. To the contrary, this court's new creation offers the public nothing more in exchange for a patent than the statutory enablement requirement already ensures. As the Supreme Court explains, the "*quid pro quo* [for a patent monopoly] is disclosure of a process or device in sufficient detail *to enable one skilled in the art to practice the invention once the period of the monopoly has expired.*" *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.,* 322 U.S. 471, 484, 64 S.Ct. 1110, 88 L.Ed. 1399 (1944) (emphasis added). What "teaching function," *Ariad,* 560 F.3d at 1370 (quoting *Univ. of Rochester,* 358 F.3d at 922), does the court propagate by telling an inventor that a patent application must show "possession as shown in the disclosure," whatever that means? Inventors, to my knowledge, are always quite certain that they possess their invention.

II.

Eli Lilly was not only new law, it also is in tension with other areas of long-established law: claim construction and blocking patents, to name just two.

The doctrine of claim construction, a doctrine that is framed by the first two paragraphs of § 112, *Phillips,* 415 F.3d at 1311–12, presents an undeniable conflict of monumental proportions. As *Phillips* confirmed, and this court has confirmed and ***1365** reconfirmed, claims must be read " 'in view of the specification' " to determine their meaning. 415 F.3d at 1315 (quoting *Markman v. Westview Instruments,* 52 F.3d 967, 979 (Fed.Cir.1995)); *see, e.g., id.* ("Claims must always be read in light of the specification. Here, the specification makes plain what the appellants did and did not invent ....") (quoting *In re Fout,* 675 F.2d 297, 300 (CCPA 1982) (alteration in original)); *Abbott Labs. v. Sandoz, Inc.,* 566 F.3d 1282, 1288 (Fed.Cir.2009) ("[T]he claims cannot enlarge what is patented beyond what the inventor has described as the invention.") (quotation omitted).

If this court followed its own rule and ensured that claims do not enlarge what the inventor has described, then the claims would never have a scope that exceeds the disclosure in the rest of the specification. Thus, this court would never find a claim that "lacks support" (again, whatever that means) in the rest of the patent document. In other words, this court's new written description doctrine only has meaning if this court ignores its own claim construction rules. This court essentially claims unfettered power to err twice—both in construing the claims so broad as to exceed the scope of the rest of the specification and then to invalidate those claims because it reads the specification as failing to "support" this court's own broad conception of the claimed subject matter.

"A 'blocking patent' is an earlier patent that must be licensed in order to practice a later patent. This often occurs, for instance, between a pioneer patent and an improvement patent." *Prima Tek II, L.L.C. v. A–Roo Co.,* 222 F.3d 1372, 1379 n. 2 (Fed.Cir.2000). The Supreme Court has long acknowledged the "well established" rule that "an improver cannot appropriate the basic patent of another and that the improver without a license is an infringer and may be sued as such." *Temco Elec. Motor Co. v. Apco Mfg. Co.,* 275 U.S. 319, 328, 48 S.Ct. 170, 72 L.Ed. 298 (1928). This blocking condition can exist even where the original patentee "failed to contemplate" an additional element found in the improvement patent. *A.B. Dick Co. v. Burroughs Corp.,* 713 F.2d 700, 703 (Fed.Cir.1983).

Blocking conditions conceivably occur often where a pioneering patent claims a genus and an improvement patent later claims a species of that genus. *See, e.g., Utter v. Hiraga,* 845 F.2d 993, 998 (Fed.Cir.1988) (holding that in an interference proceeding "[t]here is no inconsistency in awarding a generic count to one inventor, while awarding a patentably distinct species count to another."); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.,* 721 F.2d 1540, 1554 (Fed.Cir.1983) ("Assuming [the first-in-time patent is] a dominating patent, the rule of law is clear that an accused infringer's employment of the process of a dominating patent does not render that employment an anticipation of an invention described and claimed in an improvement patent."). These blocking patents often serve the market well by pressuring both inventors to license their innovations to each other and beyond.

After *Eli Lilly,* however, the value of these blocking situations will disappear unless the pioneering patentee "possessed," yet for some reason chose not to claim, the improvement. That situation, of course, would rarely, if ever, happen. *See Rochester,* 375 F.3d at 1312 (Rader, J., dissenting) ("Inventors know when they have made an invention and realize that they must properly disclose it or risk losing it entirely."). Unfortunately the new *Eli Lilly* doctrine effectively prevents this long-standing precept of patent law. For example, although "[i]mprovement and selection inventions are ubiquitous in patent law; such developments do not cast doubt on enablement of the original invention," ***1366** *CFMT, Inc. v. Yieldup Int'l Corp.,* 349 F.3d 1333, 1340 (Fed.Cir.2003), they apparently do cast doubt on the written description of the original invention. *See also Integra Lifesciences I, Ltd. v. Merck KGaA,* 331 F.3d 860, 869 (Fed.Cir.2003), *vacated on other grounds,* 545 U.S. 193, 125 S.Ct. 2372, 162 L.Ed.2d 160 (2005) ("The '525 patent is a genus patent. Such genus patents do not estop the applicant from later filing an improvement patent ... to claim species with particularly useful properties."). Without this new rule, downstream and upstream innovators in this case would have benefited from the ability to cross license. Under the new regime, mere improvements will likely invalidate genus patents. The principle of unintended consequences once again counsels against judicial adventurism.

III.

Under this new doctrine, patent applicants will face a difficult burden in discerning proper claiming procedure under this court's unpredictable written description of the invention requirement. The court talks out of both sides of its mouth as it lays out the test. On the one hand, the test seems to require the fact finder to make a subjective inquiry about what the inventor possessed. *Ante* at 1350–51. On the other, the court states that the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. But a test becomes no less subjective merely because it asks a fact finder to answer the subjective question objectively. This court still asks the fact finder to imagine what a person of skill in the art would have understood the inventor to have subjectively possessed based on the description in the specification (which of course by definition describes the exact same invention according to this court's claim construction rules).

The court makes the subjective/objective nature of the test even more confusing by perpetuating the test's status as a question of fact. Other related, objective inquiries that focus on the four corners of the specification, such as

claim construction and enablement, are questions of law. If the court is right that the written description of the invention test is objective, then either the court misclassifies written description or claim construction and enablement. Moreover, if the test were truly objective, this court would not have such trouble defining it. As it stands, the court's inadequate description of its written description requirement acts as a wildcard on which the court may rely when it faces a patent that it feels is unworthy of protection.

A reading of the statute, on the other hand, supplies a strong enablement test with a neutral, empirical, and predictable test:

> Enablement already requires inventors to disclose how to *make* (reproduce, replicate, manufacture) and how to *use* the invention (by definition rendering it a "useful art"). Therefore, because the competitor can make the invention, it can then acquire the DNA sequence or any other characteristic whenever it desires. Meantime the competitor can use, exploit, commercialize (outside the patent term) or improve upon and design around (within the patent term) as much of the invention as it cares to make. In other words, the statutory standard for sufficiency of disclosure serves masterfully the values of the patent system.

Enzo, 323 F.3d at 980–81 (Rader, J., dissenting).

In sum, the statute supplies a test for description that has operated marvelously for decades, if not centuries. If this court perceives a need for renewed attention to ***1367** description requirements, it should strengthen its enablement jurisprudence instead of making new rules. Invention of new technologies strengthens and advances the "useful arts," but invention of new doctrines frustrates and confuses the law.

LINN, Circuit Judge, with whom RADER, Circuit Judge, joins, dissenting-in-part and concurring-in-part.

The statutory arguments that the majority today enshrines fail to justify establishing a separate written description requirement apart from enablement and beyond the priority context, and fail to tether that written description requirement to a workable legal standard. For these and the reasons that follow, I respectfully dissent from Part I of the majority's opinion, and believe the appeal should have been returned to the panel for resolution of the enablement question. I take no position on the merits of Ariad's compliance with 35 U.S.C. § 112, paragraph 1; however, I concur in the affirmance of no inequitable conduct.

A. The Statutory Language

Like the majority, I start with the parties' statutory interpretations. Ariad insists that "ordinary rules of English grammar" and a "plain reading" of § 112, paragraph 1 show that the description of the invention is judged only by enablement—namely, whether it describes "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." Ariad's Principal Br. 2–3. While Lilly relies less on statutory interpretation, it responds that the text delineates two written description requirements—"of the invention" and "of the manner and process of making and using it"—but that the enablement standard applies only to the latter. Lilly's Br. 27–28. The amici take varying positions on either side of this debate. *See* Br. of Amicus Roberta Morris 4–9 (parsing statutory text to show no separate written description requirement); Br. of Amicus Christopher Cotropia 17–20 (arguing that a "plain, grammatically correct reading" mandates a distinct standard for written description).

While the parties offer vigorous arguments about the grammar of § 112, paragraph 1, the only reasonable interpretation is the one offered by Ariad, both because it conforms to the long-recognized purpose of the statute in policing new matter violations and because it tethers the "written description of the invention" to an understood standard: "such full, clear, concise, and exact terms so as to enable." Lilly remarks that statutes do not necessarily specify their own tests, and that "the legal standards for applying them are developed by courts over time." Lilly's Br. 28. Although this might be true generally, Congress did provide such a legal standard in this statute, and the majority's creation of a separate, additional

requirement—with a poorly defined standard—is unnecessary and ill advised. In my view, there is no justification for reading the statute, beyond the priority context suggested by 35 U.S.C. § 120, as requiring anything other than a written description sufficient to enable a skilled artisan to make and use the invention particularly pointed out and distinctly recited in the claims.

The enablement requirement provides an established standard for the propriety of the written description offered to support a set of claims. *See In re Wands,* 858 F.2d 731, 737 (Fed.Cir.1988) ("The term 'undue experimentation' does not appear in the statute, but it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation."). ***1368** The enablement requirement also ensures that the full extent of claims asserted by an applicant have utility, such that the public can make and use the invention recited therein. *See In re '318 Patent Infringement Litig.,* 583 F.3d 1317, 1323–24 (Fed.Cir.2009) ("Enablement is closely related to the requirement for utility.... The utility requirement prevents mere ideas from being patented.").

B. The Majority's Proposed Written Description Test

I credit the majority for acknowledging that the "possession" test "has never been very enlightening" and for attempting to clarify that "possession as shown in the disclosure" should be an "objective inquiry into the four-corners of the specification." *Maj. Op.* at 1351. Yet, given the court's concern for public notice, the opinion fails to set the boundaries for compliance with its separate written description test. Commentators have noted our use of variable and confusing vocabulary to delineate the test: that the specification demonstrate "possession," that the inventor "invented what is claimed," or that a person of ordinary skill be able to "visualize or recognize" the claimed subject matter. Donald S. Chisum, 3 *Chisum on Patents* § 7.04[1][e] (2009). Today, the majority confirms the notion that the specification must show that the inventor "actually invented the invention claimed," *Maj. Op.* at 1351, but then says that "actual 'possession' or reduction to practice outside of the specification is not enough," *id.* at 1352. If the specification's four corners control—not the inventor's subjective beliefs or activities—then an "actually invented" standard should be irrelevant. Moreover, § 112, paragraph 2 already requires separately that the claims, once issued, objectively claim "the subject matter which the applicant regards as his invention." *See Solomon v. Kimberly–Clark Corp.,* 216 F.3d 1372, 1379–80 (Fed.Cir.2000).

The language that the majority uses to explain "possession as shown in the disclosure" not only fails to justify a separate test, it also fails to distinguish the test for written description from the requirements for enablement. "[T]he level of detail required to satisfy the written description requirement," according to the majority, "varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Maj. Op.* at 1351. These considerations, however, mirror the *Wands* factors for enablement, which include "the nature of the invention," "the breadth of the claims," and "the predictability or unpredictability of the art." 858 F.2d at 737. The court attempts to distinguish enablement by observing that "although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that *have not been invented,* and thus cannot be described." *Maj. Op.* at 1352 (emphasis added). Yet, if a person of ordinary skill is enabled to make and use a novel and nonobvious invention clearly recited in the claims, I fail to see how that invention can be said to "have not been invented" or be in need of some undefined level of additional description.

C. Stare Decisis

I cannot accept the majority's conclusion that the current written description doctrine adopted in *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559 (Fed.Cir.1997), was created not by the Federal Circuit in 1997, but by the Supreme Court as early as the 19th century, and therefore carries weighty stare decisis effect. *Maj. Op.,* Parts I.B–C. In my view, Ariad thoroughly refutes these arguments.

***1369** First, the history of the Patent Acts does not reveal a separate written description requirement for original claims. Before 1836, the patent statutes did not require patents to contain claims. At that time, a patent's written description satisfied two requirements: (1) "to distinguish the same [the invention] from all other things before known," and (2) "to enable any person skilled in the art or

science ... to make, compound, and use the same." Act of Feb. 27, 1793, 1 Stat. 318, 321–22, ch. 11, § 3. Accordingly, the Supreme Court recognized in *Evans v. Eaton* that a patent's written description performed the "two objects" to "make known the manner of constructing the machine ... so as to enable," and to "put the public in possession of what the party claims as his own invention." 7 Wheat. 356, 20 U.S. 356, 433–34, 5 L.Ed. 472 (1822). Subsequently, the 1836 Act introduced claims to patents by requiring an applicant to "particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery," and simultaneously removed the need for the written description to "distinguish" the invention from "all other things before known." Act of July 4, 1836, 5 Stat. 117, 119, ch. 357, § 6. Lilly argues that, prior to the 1836 Act, *Evans* equated "distinguishing" the invention to a modern-day written description requirement. Lilly's Br. 5. However, Ariad correctly points out that Lilly mistakenly cites the reported attorney argument for that proposition, not the Court's opinion. Ariad's Reply Br. 8. More importantly, even if Lilly were correct that the Supreme Court previously enforced a quasi-written description requirement, with the advent of patent claims after *Evans,* a patent's written description no longer served to "distinguish" the invention from the prior art.

Despite this statutory background, the majority accepts Lilly's characterization of post–1836 precedent to conclude that "after the 1836 Act added the requirement for claims, the Supreme Court applied this description requirement separate from enablement." *Maj. Op.* at 11. For example, the majority and Lilly rely on *Schriber–Schroth Co. v. Cleveland Trust Co.,* 305 U.S. 47, 59 S.Ct. 8, 83 L.Ed. 34 (1938), which dealt with two patents to Gulick and Maynard for pistons in internal combustion engines. Gulick described "extremely rigid" web elements in the pistons in his original application, but later amended the application to include "flexible" webs. *Id.* at 56, 59 S.Ct. 8. While Maynard did not amend his application, flexible webs were "neither described in Maynard's specifications nor mentioned in his claims." *Id.* at 60, 59 S.Ct. 8. The Court held that neither patent could claim flexible web elements because neither disclosed that feature.

The majority claims: "Although the [*Schriber*] Court did not expressly state that it was applying a description of the invention requirement separate from enablement, that is exactly what the Court did." *Maj. Op.* at 1346; *see also* Lilly's Br. 11–14. But the Court rejected Gulick's amended claims because they expanded his original disclosure to encompass "new matter beyond the scope of the device described in the application *as filed.*" *Schriber,* 305 U.S. at 58, 59 S.Ct. 8 (emphasis added). The Court also stressed that "the application for a patent cannot be broadened by amendment so as to embrace an invention not described in the application as filed." *Id.* at 57, 59 S.Ct. 8. Thus, *Schriber* required that the invention be "described and explained," *id.,* but did so to establish priority.

The majority also rests on *O'Reilly v. Morse,* 56 U.S. (15 How.) 62, 120, 14 L.Ed. 601 (1854), where the Supreme Court invalidated one of Samuel Morse's telegraphy-related claims for claiming "what he ***1370** has not described." *Maj. Op.* at 1346 n.4. Lilly cites passages from *Morse* and highlights every instance of the words "description" or "described." Lilly's Br. 8. However, this places too much stock in these words and assumes that "describes" meant in 1854 what the majority would like it to mean today. Morse's description was deficient because it did not enable the full scope of his broadest claim (to all possible electrical telegraphs), not because it failed the equivalent of a present-day "possession" test for written description.

The majority also suggests that the Supreme Court ratified our current written description doctrine in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002). But that decision addressed the scope of prosecution history estoppel under the doctrine of equivalents. The extent of the Court's allusion to written description is a recitation that applications must "describe, enable, and set forth the best mode," and that "exclusive patent rights are given in exchange for disclosing the invention to the public." *Id.* at 736, 122 S.Ct. 1831. Neither of these statements is a holding that written description applies to originally filed claims, or even that enablement is not the sole measure of disclosure. With all due respect, characterizing *Festo* as an endorsement of modern written description is at best misplaced.

Until our 1997 decision in *Lilly,* we applied a written description doctrine from § 112, paragraph 1 to control patent applicants' claims to priority, but not to invalidate originally filed claims, and without any perceived inconsistency with the statute. *E.g., In re Rasmussen,* 650 F.2d 1212, 1214 (CCPA 1981) ("The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, therefore, is § 112, first paragraph...."). Only since *Lilly* have we forced original claims over a description hurdle extending beyond enablement.

D. Original Claims

In addition to rejecting the majority's precedent-based arguments, I part ways with the majority's policy justifications for applying written description to original claims. The majority accepts Lilly's argument that, "while an original claim is part of the specification, this fact does not mean that original claims must always be an adequate written description of the invention." Lilly's Br. 35. This debate is not new. *See Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1307 (Fed.Cir.2004) (Lourie, J., concurring) ("Thus, the fact that a statement of an invention is in an original claim does not necessarily end all inquiry as to the satisfaction of the written description requirement."). However, the policy reasons for applying such a requirement to original claims remain unconvincing.

It is beyond dispute that original claims are part of a patent's disclosure. *See id.* (Lourie, J., concurring) ("As for the proposition that an original claim is part of the written description, that is clear."). And our predecessor court repeatedly held that, as part of the disclosure, "original claims constitute their own description." *In re Koller*, 613 F.2d 819, 823 (CCPA 1980); *see also In re Smith*, 481 F.2d 910, 914 (CCPA 1973) ("Where the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied."); *In re Gardner*, 475 F.2d 1389, 1391 (CCPA 1973) (holding that an original claim sufficiently described itself, and that "[n]othing more is necessary for compliance with the description requirement of the first paragraph of 35 U.S.C. § 112"), *reh'g denied*, ***1371** 480 F.2d 879, 879–80 (CCPA 1973) ("Under these circumstances, we consider the original claim in itself adequate 'written description' of the claimed invention."). Thus, as I have said before, "[f]or original claims, ... the claim itself evidenc[es] possession of the invention as of the filing date." *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 988 (Fed.Cir.2002) (Linn, J., dissenting).

It is inconsistent to say that on its filing date, a patent does not show that the inventor "possessed" subject matter that the claims actually encompass and the specification fully enables. Doing so perpetuates an unnecessary tension between the claims and the written description as the definition of a patented invention. *See* 35 U.S.C. § 112, para. 2 (requiring claims "particularly pointing out and distinctly claiming the subject matter"); *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339, 81 S.Ct. 599, 5 L.Ed.2d 592 (1961) (observing that "the claims made in the patent are the sole measure of the grant"). Indeed, the majority reinforces the confusing notion that the primary purpose of claims is "to provide notice of the boundaries of the right to exclude ... not to describe the invention." *Maj. Op.* at 1347; *cf.* Br. of Amicus Oskar Liivak 15 ("The claims are not the invention as a logical, conceptual and practical matter."). Again, since the 1836 Patent Act, claims have served the purpose of "distinguishing" the invention, while the specification as a whole must "enable."

The fear that even original claims might "claim[ ] the invention by what it does rather than what it is," Lilly's Br. 35, is unfounded because all claims must satisfy enablement and other requirements for patentability. The majority agrees that "many original claims will satisfy the written description requirement," but expresses concern that applicants may use "functional language to define the boundaries of a claimed genus," without disclosing "species sufficient to support a claim." *Maj. Op.* at 1349. I agree that such claims should be invalid—but enablement polices those claims effectively. Any claim that uses purely functional language, or covers a broad genus without sufficient supporting examples, will not be enabled. *E.g., In re Vaeck*, 947 F.2d 488, 495–96 (Fed.Cir.1991) (affirming enablement rejection of genus claims).

Lilly and several amici caution that the written description doctrine protects the public by requiring patentees to provide specific notice of the scope of their inventions. *See, e.g.*, Br. of Amicus Medtronic, Inc. 11–12. This concern is also misplaced. Generally, under 35 U.S.C. § 122(b), patent applications publish eighteen months "from the earliest filing date for which a benefit is sought." Therefore, the public receives notice of original claims within a specified time. *See* Br. of Amicus Monsanto Co. 8 ("Regardless of its breadth, the language of an original claim puts skilled artisans on notice that the inventor is claiming such subject matter as the inventor's own invention."). Even if the application does not publish before the patent issues, the original claims remain part of the public prosecution history and notify the public of the invention's scope.

The government submitted an amicus brief in which it asserted that the written description doctrine is "necessary to permit USPTO to perform its basic examination function" and claimed that the Patent Office applies § 112, paragraph 1 to over "400,000 patent applications each year." Br. of Amicus United States 19–20. However, at oral argument the government could not cite the number of applications that the PTO annually rejects on written description grounds and cannot reject on another basis. *See* Oral Arg. at 22:42–24:50. ***1372** The government also agreed that "enablement is available to

address a large number of these problems." *Id.* at 28:01–32. Indeed, a study released after argument that reviewed over 2800 appeals to the Board of Patent Appeals and Interferences ("BPAI") during 2009 found that only 4.3% of those cases decided written description issues, and that none of those outcomes would change if the PTO could continue to issue new matter rejections under 35 U.S.C. § 132. Dennis D. Crouch, *An Empirical Study of the Role of the Written Description Requirement in Patent Prosecution* 2 (Univ. of Mo. Sch. of Law Legal Studies Research Paper No.2010–06, 2010), *available at* http://ssrn. com/abstract=1554949. The study concludes that, "in the context of patent applications appealed to the BPAI, the impact of the separate written description requirement is negligible apart from its role in policing the addition of new matter." *Id.* at 3. While this research only addressed a small sample of applications and did not consider written description rejections that applicants overcome or do not appeal, these results and the government's lack of empirical evidence undermine the government's hypothesis that our patent examination system would grind to a halt if written description no longer applies to originally filed claims. The Patent Office survived well enough before 1997, when it was understood that written description was a basis for rejecting broadening amendments to claims or specifications, not original claims. *See Rasmussen,* 650 F.2d at 1214.

* * *

The court granted the petition for rehearing in this case to address whether § 112, paragraph 1 contains a written description requirement separate from an enablement requirement and, if so, the scope and purpose of such a requirement. In affirming such requirement, the majority leaves unanswered once again the critical question first presented to the panel of whether the asserted claims of the '516 patent meet the enablement requirement. In my view, the question before the en banc court should have been answered in the negative and the appeal returned to the panel for resolution of the enablement question and Lilly's remaining invalidity and noninfringement defenses. I concur, however, in the majority's reinstatement of the panel's affirmance of no inequitable conduct. For these reasons, I respectfully dissent from Part I of the majority opinion, concur in the ruling of no inequitable conduct, and take no position on the merits of Ariad's compliance with 35 U.S.C. § 112, paragraph 1.

All Citations

598 F.3d 1336, 94 U.S.P.Q.2d 1161

289 F.3d 1367
United States Court of Appeals, Federal Circuit.

CROWN OPERATIONS INTERNATIONAL, LTD. and Marshall H. Krone, Plaintiffs–Appellants,
v.
SOLUTIA INC., Defendant–Appellee.

No. 01–1144
|
DECIDED: May 13, 2002.
|
Rehearing Denied: June 10, 2002.

Synopsis
Competitor of holder of patents for layered films used to create safety and solar control glass brought suit seeking declaratory judgment that patents were invalid. The United States District Court for the Western District of Wisconsin, John C. Shabaz, J., granted summary judgment denying relief. Competitor appealed. The Court of Appeals, Gajarsa, Circuit Judge, held that: (1) two percent limitation for visible reflectance contribution that was claimed in first patent was not inherent in, and thus was not anticipated by, existing patent; and (2) first patent was not invalid for obviousness; but (3) fact issue as to whether second patent satisfied enablement requirement precluded summary judgment.

Affirmed in part, reversed in part, and remanded.

Procedural Posture(s): On Appeal; Motion for Summary Judgment.

West Headnotes (25)

[1] **Federal Courts** Summary judgment

170BFederal Courts
170BXVIICourts of Appeals
170BXVII(K)Scope and Extent of Review
170BXVII(K)2Standard of Review
170Bk3576Procedural Matters
170Bk3604Judgment
170Bk3604(4)Summary judgment
(Formerly 170Bk776)

Court of Appeals reviews a district court's grant of summary judgment without deference. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

1 Case that cites this headnote

[2] **Summary Judgment** Favoring nonmovant; disfavoring movant

368HSummary Judgment
368HIVAscertaining Whether Fact Issue Exists
368Hk73Presumptions and Inferences
368Hk75Favoring nonmovant; disfavoring movant
(Formerly 170Ak2543)

On a motion for summary judgment, the evidence must be viewed in the light most favorable to the party opposing the motion, with doubts resolved in favor of the nonmovant. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

21 Cases that cite this headnote

[3] **Summary Judgment** Shifting burden
Summary Judgment Speculation or conjecture; mere assertions, conclusions, or denials

368HSummary Judgment
368HIVAscertaining Whether Fact Issue Exists
368Hk76Burden of Proof
368Hk78Shifting burden
(Formerly 170Ak2546)
368HSummary Judgment
368HIVAscertaining Whether Fact Issue Exists
368Hk95Speculation or conjecture; mere assertions, conclusions, or denials
(Formerly 170Ak2546)

Once party moving for summary judgment has satisfied its initial burden, the opposing party must establish a genuine issue of material fact and cannot rest on mere allegations, but must present actual evidence. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

66 Cases that cite this headnote

[4] **Summary Judgment**🔑What constitutes "genuine" issue or dispute

368HSummary Judgment
368HIIIGrounds for Summary Judgment; Factors Considered
368Hk42Absence of Issue of Fact
368Hk46What constitutes "genuine" issue or dispute
(Formerly 170Ak2470.1)

Issues of fact are genuine, and thus sufficient to preclude grant of summary judgment, only if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

6 Cases that cite this headnote

[5] **Summary Judgment**🔑What Constitutes "Material" Fact

368HSummary Judgment
368HIIIGrounds for Summary Judgment; Factors Considered
368Hk42Absence of Issue of Fact
368Hk47What Constitutes "Material" Fact
368Hk47(1)In general
(Formerly 170Ak2470.1)

A disputed fact is material, so that summary judgment may not be granted, if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

3 Cases that cite this headnote

[6] **Patents**🔑Single reference disclosing every element or limitation of claim

291Patents
291IIPatentability and Validity
291II(C)Novelty; Anticipation
291II(C)1In General
291k483Prior Art and Relation of Claimed Invention Thereto
291k489Number of Prior Art References; Combinations
291k489(2)Single reference disclosing every element or limitation of claim
(Formerly 291k72(1))

A patent is invalid for anticipation when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference.

37 Cases that cite this headnote

[7] **Patents**🔑Contents and Sufficiency of Prior Art in General

291Patents
291IIPatentability and Validity
291II(C)Novelty; Anticipation
291II(C)1In General
291k483Prior Art and Relation of Claimed Invention Thereto
291k487Contents and Sufficiency of Prior Art in General
291k487(1)In general
(Formerly 291k72(1))

To render a patent invalid for anticipation, an anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention.

48 Cases that cite this headnote

[8] **Patents**🔑In general; multiple factors
Patents🔑Questions of law or fact

291Patents
291IIPatentability and Validity
291II(E)Obviousness; Lack of Invention
291II(E)2Factors Considered
291k681In general; multiple factors
(Formerly 291k36.1(1), 291k16(3), 291k16(2))
291Patents
291IIPatentability and Validity
291II(E)Obviousness; Lack of Invention
291II(E)4Evidence and Determination

291k800Questions of law or fact
(Formerly 291k16.13)

Obviousness of device or method claimed in a patent is a legal conclusion based on underlying facts of four general types, all of which must be considered by the trier of fact: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) any objective indicia of nonobviousness.

26 Cases that cite this headnote

[9] **Patents**Combination of prior art references; "teaching, suggestion, or motivation" test
PatentsTime of evaluation; hindsight

291Patents
291IIPatentability and Validity
291II(E)Obviousness; Lack of Invention
291II(E)2Factors Considered
291k682Prior Art and Relation of Claimed Invention Thereto
291k685Combination of prior art references; "teaching, suggestion, or motivation" test
(Formerly 291k26(1))
291Patents
291IIPatentability and Validity
291II(E)Obviousness; Lack of Invention
291II(E)2Factors Considered
291k720Time of evaluation; hindsight
(Formerly 291k16(4))

A determination of obviousness of method of device for which patent protection is sought cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention; rather, there must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor.

31 Cases that cite this headnote

[10] **Patents**Written Description Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)

Inquiry into whether patent is invalid based on lack of a written description is a factual one and must be assessed on a case-by-case basis. 35 U.S.C.A. § 112.

[11] **Patents**Written Description Requirement
PatentsPossession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention
(Formerly 291k99)

In order to satisfy the written description requirement, the patent disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue; nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. 35 U.S.C.A. § 112.

10 Cases that cite this headnote

[12] **Patents**Possession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General

291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention
(Formerly 291k99)

Satisfaction of possession test, standing alone, is not always sufficient to meet the written description requirement for patent protection. 35 U.S.C.A. § 112.

[13] **Patents**Disclosure as directed to one skilled in the art

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(2)Disclosure as directed to one skilled in the art
(Formerly 291k99)

Written description requirement for a patent is satisfied by the patentee's disclosure of such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention; put another way, one skilled in the art, reading the original disclosure, must reasonably discern the limitation at issue in the claims. 35 U.S.C.A. § 112.

13 Cases that cite this headnote

[14] **Patents**Questions of law or fact

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k908Enablement Requirement
291k908(6)Questions of law or fact
(Formerly 291k314(5))

Whether a patent claim is enabled is a question of law, although based upon underlying factual findings. 35 U.S.C.A. § 112.

12 Cases that cite this headnote

[15] **Patents**Miscellaneous products and devices

291Patents
291IIPatentability and Validity
291II(C)Novelty; Anticipation
291II(C)2Particular Fields of Invention
291k567Miscellaneous products and devices
(Formerly 291k66(1.25))

Two percent limitation for visible reflectance contribution that was claimed in patent for solar control film used in safety and solar control glass was not inherent in, and thus was not anticipated by, existing patent, which disclosed other limitations claimed in patent, but did not claim two percent limitation.

1 Case that cites this headnote

[16] **Patents**Inherent anticipation

291Patents
291IIPatentability and Validity
291II(C)Novelty; Anticipation
291II(C)1In General
291k483Prior Art and Relation of Claimed Invention Thereto
291k490Inherent anticipation
(Formerly 291k65)

Inherency of a disclosure in prior art, as will permit a subsequent patent to be rendered invalid due to anticipation, may not be established by probabilities or possibilities, and the mere fact that a certain thing may result from a given set of circumstances is not sufficient.

5 Cases that cite this headnote

[17] **Summary Judgment**Burden of Proof
Summary Judgment Sufficiency of Evidence

368HSummary Judgment

368HIVAscertaining Whether Fact Issue Exists
368Hk76Burden of Proof
368Hk77In general
(Formerly 170Ak2544)
368HSummary Judgment
368HIVAscertaining Whether Fact Issue Exists
368Hk79Sufficiency of Evidence
368Hk80In general
(Formerly 170Ak2544)

Party moving for summary judgment has the burden to show that there is an absence of evidence to support the non-moving party's case, and the non-moving party must affirmatively demonstrate by specific factual allegations that a genuine issue of material fact exists for trial. Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

94 Cases that cite this headnote

[18] **Patents**Degree of proof

291Patents
291IVPatent Applications and Proceedings
291IV(D)Conclusiveness and Effect of Administrative Decisions
291k1116Sufficiency of Evidence to Offset Effect of Decision
291k1119Degree of proof
(Formerly 291k112.5)

A patent enjoys a presumption of validity, which can be overcome only through clear and convincing evidence. 35 U.S.C.A. § 282.

1 Case that cites this headnote

[19] **Patents**Miscellaneous products and devices

291Patents
291IIPatentability and Validity
291II(E)Obviousness; Lack of Invention
291II(E)3Particular Fields of Invention
291k787Miscellaneous products and devices
(Formerly 291k16.14)

Patent for solar control film used in safety and solar control glass, which described a film which contributed no more than about two percent visible reflectance, was not invalid for obviousness; no showing was made that prior art contained a teaching, suggestion, or motivation to reduce the reflectance contribution of the solar control film in question.

3 Cases that cite this headnote

[20] **Patents**Written Description Requirement
PatentsEnablement Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k908Enablement Requirement
291k908(1)In general
(Formerly 291k99)

Written description and enablement requirements for patents, while related and springing from the same factual predicates, each carry a separate purpose. 35 U.S.C.A. § 112.

3 Cases that cite this headnote

[21] **Patents**Enablement Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k908Enablement Requirement
291k908(1)In general
(Formerly 291k99)

Purpose of the enablement requirement for patents is to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. 35 U.S.C.A. § 112.

3 Cases that cite this headnote

[22] **Patents** Written Description Requirement
Patents Enablement Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k908Enablement Requirement
291k908(1)In general
(Formerly 291k99)

A patent specification may contain a disclosure that is sufficient to enable one skilled in the art to make and use the invention, and yet fail to comply with the description of the invention requirement. 35 U.S.C.A. § 112.

4 Cases that cite this headnote

[23] **Patents** Patentability and Validity

291Patents
291VIIPatent Infringement
291VII(C)Actions
291VII(C)6Judgment
291k1932Summary Judgment
291k1935Particular Cases
291k1935(4)Patentability and Validity
291k1935(5)In general
(Formerly 170Ak2508)

Genuine issue of material fact as to whether a person of ordinary skill in the pertinent art could make or use invention claimed in patent for method of eliminating optical distortion in safety and solar control glass, as would allow patent to satisfy enablement requirement, precluded summary judgment in competitor's suit seeking declaratory judgment regarding validity of patent. 35 U.S.C.A. § 112; Fed.Rules Civ.Proc.Rule 56(c), 28 U.S.C.A.

6 Cases that cite this headnote

[24] **Patents** In general; utility

291Patents
291XPatents Enumerated
291k2091In general; utility
(Formerly 291k328(2))

US Patent 4,017,661, US Patent 5,091,258. Cited.

1 Case that cites this headnote

[25] **Patents** In general; utility

291Patents
291XPatents Enumerated
291k2091In general; utility
(Formerly 291k328(2))

US Patent 4,973,511. Not Invalid.

Attorneys and Law Firms

***1370** Joseph T. Leone, DeWitt Ross and Stevens, S.C., of Madison, WI, argued for plaintiffs-appellants. With him on the brief was Joseph A. Ranney.

Gregory E. Upchurch, Thompson Coburn LLP, of St. Louis, MO, argued for defendant-appellee. With him on the brief were Kenneth R. Heineman, and Dudley W. Von Holt.

Before LOURIE, CLEVENGER, and GAJARSA, Circuit Judges.

Opinion

GAJARSA, Circuit Judge.

Crown Operations International, Ltd., and Mr. Marshall H. Krone (collectively "Crown"), appeal the decision of the United States District Court for the Western District of Wisconsin denying Crown declaratory relief that Solutia's U.S. Patent No. 4,973,511 ("the '511 patent") is invalid for lack of novelty and non-obviousness, and that Solutia's U.S. Patent No. 5,091,258 ("the '258 patent") is invalid for lack of enablement and written description. *Crown Operations Int'l, Ltd. v. Solutia, Inc.,* No. 99–C–802–S, slip op. at 8 (W.D.Wis. Aug. 30, 2000) (memorandum decision and order granting summary judgment) ("*August 30 Order* "); *Crown Operations Int'l, Ltd. v. Solutia, Inc.,* No. 99–C–802–S, slip op. at 24, 27 (W.D.Wis. Aug. 22, 2000) (same) ("*August 22 Order* "). Because we find no error in the district court's opinion with respect to the '511 patent, we affirm that portion of the district court's decision. However, because the district court erred in its analysis of enablement for the '258 patent, and did not address the written description issue for the '258 patent, we vacate the district court's grant of summary judgment on that issue and remand for additional proceedings consistent with this opinion.

I. BACKGROUND

The patents at issue in this appeal relate to layered films used to create safety and solar control glass. An example is an automobile windshield. Most windshields have two layers of glass with a multi-layer film between the glass layers. The multi-layer film adds properties to the glass assembly, such as impact resistance or providing a conductive layer that facilitates defrosting the windshield. An inner layer of the film has solar control properties to selectively reflect, absorb (and thus convert to heat) or transmit defined percentages of certain wavelengths of light. This inner layer is called the solar control film. It is made of a substrate coated by one or more layers of metal or metallic substances. '511 patent, col. 3, l. 64 to col. 4, l. 2. Typically, manufacturers laminate the solar control film between layers of plasticized polyvinyl butyral ("PVB") (sometimes called the "safety film") in a process known as encapsulation. Then, the encapsulated solar control film is sandwiched between two pieces of glass for a final assembly of multi-layer glass with safety and solar control properties.

A. The '511 Patent

The '511 patent is directed to the problem that the metal-coated substrate, *i.e.,* solar control film, tends to wrinkle during encapsulation causing visual distortions. The '511 patent claims to mask the wrinkles from detection by the human eye by ***1371** limiting to two percent or less the visible light reflection contribution of the solar control film compared to reflection from a complete assembly of glass, PVB and solar control film. '511 patent, col. 4, ll. 46–49, col. 8, l. 66 to col. 9, l. 6, col. 14, l. 67 to col. 15, l. 2. Figure 1 from the '511 patent, set forth below, shows the layers in a complete assembly.

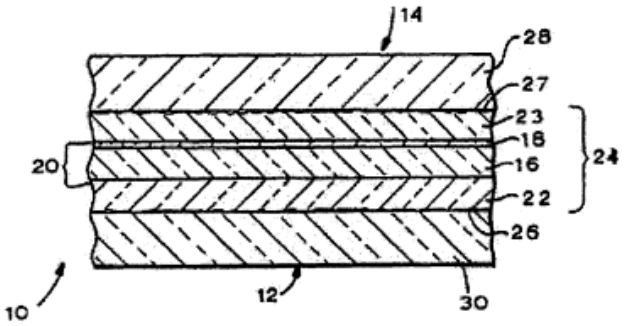


FIG. 1

FIG. 1

The complete safety and solar control glass assembly 10 includes two outer glass layers 28 & 30, PVB layers 22 & 23, and the solar control film 20. The solar control film is comprised of a substrate layer 16 and solar control coating 18. '511 patent, col. 3, ll. 41–53, col. 7, ll. 2–4, col. 10, l. 15. Figure 3 from the '511 patent, set forth below, shows the sub-layers of the solar control coating 18.

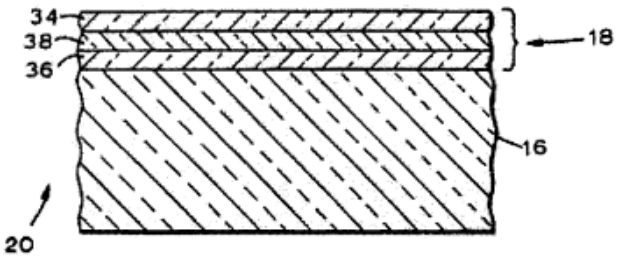


FIG. 3

FIG. 3

Layer 18 is made of multiple sub-layers. Layers 34 and 36 are metal oxide, and layer 38 is metal. '511 patent, col. 5, ll. 12–14. In addition, the ' 511 patent notes that "[p]rior automotive windshields have visible light reflection contributions for their solar films of three percent or greater." Further, it relates that the primary method of achieving a low solar control film reflectance contribution is by providing a specially-designed solar coating. '511 patent, col. 4, ll. 56–65.

On December 16, 1999, Crown sued Solutia (the "Initial Complaint"), seeking, among various other relief, a declaration that the '511 patent was invalid for anticipation and obviousness. Upon the parties' cross-motions for summary judgment, the district court found the '511 patent not anticipated and not invalid for obviousness. *August 22 Order* at 24, 27. We discuss herein only those portions of the *August 22 Order* relevant to the issues on appeal, which relate solely to the summary judgment finding that the '511 patent was not ***1372** invalid on the grounds of anticipation and obviousness.

Claim 1, the only independent claim of the '511 patent, is set forth below, with the element numbers from Figure 1 inserted into the claim.

> 1. A composite solar/safety film **[24]** for use in a laminated window assembly **[10]** comprising:
>
> a flexible, transparent plastic substrate layer **[16]** having a carrier surface and an opposing back surface;
>
> a multilayer solar control coating **[18]** on said carrier surface, said coated substrate defining a solar control film **[20]**; and
>
> at least one flexible, transparent, energy absorbing plastic safety layer **[23 and/or 22]** bonded to a surface of said solar control film;
>
> wherein said ***solar control film contributes no more than about 2% visible reflectance,*** based on total visible incident radiation, in a laminated window assembly containing said composite solar/safety film laminated to at least one rigid transparent member **[30 and/or 28].**

'511 patent, col. 14, l. 57 to col. 15, l. 4 (emphasis added and emphasized numbers added to identify elements shown in Figure 1 above).

Crown argued that U.S. Patent No. 4,017,661 to Gillery (the "Gillery patent") anticipates the '511 patent. The district court held otherwise, because, while the Gillery patent discloses the first three limitations of claim 1 of the '511 patent, it does not disclose the two percent visible reflectance limitation. The court found that neither the Gillery patent claims nor its description expressly disclose a two percent limit on reflectance contribution from the solar control film layer. Crown argued that the two percent limitation was inherently present in the Gillery patent's teachings because the Gillery patent disclosed an assembly with PVB layers, substrate layer, and substrate metal-coating—arguably of the same composition and thickness of the films disclosed by the '511 patent. Thus, Crown argued, because the structure, thickness and materials of the assembly were the same or within the same range(s), the Gillery patent must inherently disclose a two percent limitation. The district court rejected this argument because it found that none of the embodiments disclosed by the Gillery patent meet the two percent visible light reflectance limit.[1]

[1] The district court, applying a similar analysis, also found that UK Patent Application GB 2 057 355 (the "UK patent") did not anticipate the '511 patent because it did not have the two percent limitation.

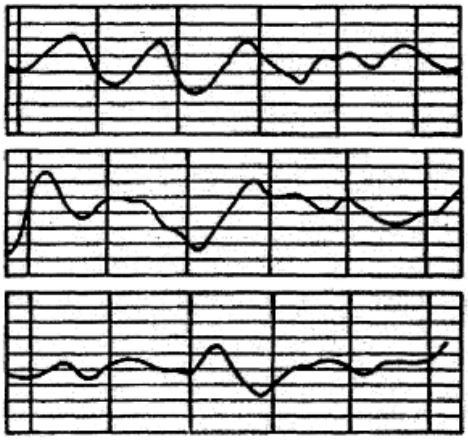
In its *August 22 Order,* the district court also held that the '511 patent was not rendered invalid for obviousness by Gillery or the other prior art cited by Crown because no prior art discloses: (i) that reflectance below two percent will mask wrinkles; (ii) a solar control film layer with reflectance below two percent; or (iii) any suggestion, motivation or teaching to reduce solar control film visible light reflectivity below two percent. Although the prior art generally sought to reduce visible light reflectivity, it also taught disadvantages of a very thin metal-coating on the substrate, including sacrificing infrared reflectivity. Thus, it taught that the proper compromise to achieve the conflicting goals of infrared (non-visible light) reflectance, visible light transmission and conductivity ***1373** was a solar control film with a visible light reflectivity greater than two percent.

B. The '258 Patent

The '258 patent is directed at eliminating optical distortion, called "applesauce," in safety and solar control glass assemblies of the type discussed above for the '511 patent. The '258 patent discloses a method to control distortion otherwise caused by the safety and solar film layer by measuring and controlling the texture of the surface of the PVB layers. The method expresses texture

using a "wave index" and a "roughness value." The wave index calculation is at issue in this appeal. Wave index indicates the relative waviness of the surface of the PVB. Determining wave index involves measuring the surface of the PVB and then aggregating the measurements into a single number, the wave index, through a calculation purportedly described in the '258 patent.

The '258 patent directs one to use an instrument to physically measure the waviness of the surface of the PVB and capture the measurement into an electronic "trace line" representing the contours of the PVB surface. '258 patent, col. 7, II. 54–65. Since the "trace line" is stored electronically, a computer program is used to calculate wave index from the trace. Three figures from the '258 patent, given below, provide examples of PVB surface trace lines.



The rules for calculating the wave index implement a "smoothing" function. The smoothing process seeks to eliminate minor inflection points (peaks or valleys) to simplify the calculation of wave index. '258 patent, col. 7, I. 66 to col. 8, I. 2.

In the Initial Complaint, Crown sought a declaration that the '258 patent was invalid for anticipation and obviousness. Then, on May 26, 2000, Crown amended the complaint (the "Amended Complaint") to additionally claim in Count VI that the '258 patent is invalid under 35 U.S.C. § 112, first paragraph, because it lacked enablement and written description due to ambiguities in the disclosed wave index calculation. In its *August 22 Order,* the district court found the '258 patent not anticipated and not invalid for obviousness. *August 22 Order* at 28–29.

With respect to Count VI of Crown's amended complaint, Solutia moved for ***1374** summary judgment on Crown's enablement and written description claim. Crown opposed Solutia's summary judgment motion, arguing that the '258 patent did not meet the enablement and written description requirements. The district court found the '258 patent not invalid for lack of enablement, but did not discuss in its opinion the written description requirement. *August 30 Order* at 8–13. We discuss herein only those portions of the *August 30 Order* relevant to the issues on appeal, which relate to summary judgment finding the '258 patent not invalid on the grounds of enablement and the procedural disposition of the written description issue.

Claim 1 of the '258 patent is set forth below. In the language of this claim, "laminate" refers to the complete glass, PVB and solar control film assembly, and "functional performance layer" refers to the solar control coating. '258 patent, col. 3, II. 45–65.

> 1. A laminate which is substantially free of reflected distortion when used in a safety glazing comprising:
>
> a transparent, thermoplastic substrate layer, optionally surface treated or coated, bearing one or more functional performance layers; and
>
> at least one layer of plasticized polyvinyl butyral bonded on one side to a functional performance layer or the substrate layer and having a roughened deairing surface on its other side characterized by a roughness value, Rz, of at least 10 micrometers;
>
> said at least one plasticized polyvinyl butyral [PVB] layer, before bonding to the substrate layer or functional performance layer, ***possessing low surface waviness on each side characterized by a wave index value, WI, of less than 15,000 square micrometers.***

'258 patent, col. 12, II. 2–16 (emphasis added).

Crown argued that the rules disclosed by the '258 patent for calculating wave index are not sufficiently precise to enable a person of ordinary skill in the art to practice the '258 patent without undue experimentation. The wave index calculation as described by the '258 patent is set forth below.

> In this regard, considering the waviness profile as a series of peaks and valleys, the smoothing rules of the program consider an inflection point to be a true peak or valley if it is: i) at least 100 micrometers away from the immediately preceding prior peak or valley and ii) at least 0.5

> micrometer above or below the immediately preceding prior peak or valley, a valley being at least 0.5 micrometer below the immediately preceding prior peak. Pitch (P) is the distance between one valley and the next valley or in other words across the base of a peak. Average amplitude (H avg) and average pitch (P avg) are determined by the program for the smoothed trace of ten 12.5 mm tracing lengths (the second five lengths being 90 ◦ to the first five lengths). From the average of the averaged H's and P's, a WI value is computed from the equation: Wave Index (WI) = (H avg) × (P avg) where H avg and P avg are in microns.

'258 patent, col. 8, II. 3–19.

Crown asserted that according to the disclosed wave index "calculation," one of ordinary skill in the pertinent art would not know whether to instruct the smoothing program to disregard a peak by comparing it to an immediately preceding peak, or to a valley. The district court held that common sense and the clarifying clause "a valley being at least 0.5 micrometer ***1375** below the immediately preceding prior peak" defeated Crown's argument. Thus, the district court held that the alleged grammatical ambiguities in the rules disclosed for calculating wave index did not invalidate the patent for lack of enablement.

Crown timely appealed the district court's two orders, raising the issues of anticipation and obviousness of the '511 patent, and lack of enablement and written description of the '258 patent. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. STANDARD OF REVIEW

[1] [2] [3] [4] [5] We review a district court's grant of summary judgment without deference. *Atmel Corp. v. Info. Storage Devices, Inc.,* 198 F.3d 1374, 1378, 53 USPQ2d 1225, 1227 (Fed.Cir.1999). Summary judgment is appropriate when the moving party demonstrates that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett,* 477 U.S. 317, 322–23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). On summary judgment, the evidence must be viewed in the light most favorable to the party opposing the motion, *Poller v. Columbia Broad. Sys., Inc.,* 368 U.S. 464, 473, 82 S.Ct. 486, 7 L.Ed.2d 458 (1962), with doubts resolved in favor of the nonmovant, *Cantor v. Detroit Edison Co.,* 428 U.S. 579, 582, 96 S.Ct. 3110, 49 L.Ed.2d 1141 (1976); *Transmatic, Inc. v. Gulton Indus., Inc.,* 53 F.3d 1270, 1274, 35 USPQ2d 1035, 1038 (Fed.Cir.1995). Once the moving party has satisfied its initial burden, the opposing party must establish a genuine issue of material fact and cannot rest on mere allegations, but must present actual evidence. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). Issues of fact are genuine only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *Id.; General Mills, Inc. v. Hunt–Wesson, Inc.,* 103 F.3d 978, 980, 41 USPQ2d 1440, 1442 (Fed.Cir.1997).

[6] [7] A patent is invalid for anticipation when the same device or method, having all of the elements contained in the claim limitations, is described in a single prior art reference. *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed.Cir.1989); *Perkin–Elmer Corp. v. Computervision Corp.,* 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed.Cir.1984). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention. *See In re Spada,* 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed.Cir.1990); *Diversitech Corp. v. Century Steps, Inc.,* 850 F.2d 675, 678, 7 USPQ2d 1315, 1317 (Fed.Cir.1988).

[8] Obviousness is a legal conclusion based on underlying facts of four general types, all of which must be considered by the trier of fact: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness. *See Graham v. John Deere Co.,* 383 U.S. 1, 17–18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966); ***1376** *Continental Can Co. USA, Inc. v. Monsanto Co.,* 948 F.2d 1264, 1270, 20 USPQ2d 1746, 1750–51 (Fed.Cir.1991); *Panduit Corp. v. Dennison Mfg. Co.,* 810 F.2d 1561, 1566–68, 1 USPQ2d 1593, 1594 (Fed.Cir.1987).

[9] "Determination of obviousness cannot be based on the

hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." *ATD Corp. v. Lydall, Inc.,* 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed.Cir.1998). There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. *See Ruiz v. A.B. Chance Co.,* 234 F.3d 654, 665, 57 USPQ2d 1161, 1167 (Fed.Cir.2000); *ATD Corp.,* 159 F.3d at 546, 48 USPQ2d at 1329; *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.,* 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed.Cir.1994) ("When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination.").

[10] [11] [12] [13] The written description inquiry is a factual one and must be assessed on a case-by-case basis. *See Vas–Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1116 (Fed.Cir.1991) (quoting *In re Smith,* 59 C.C.P.A. 1025, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis."). In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue. *See Fujikawa v. Wattanasin,* 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed.Cir.1996). Nonetheless, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention, *Vas–Cath Inc.,* 935 F.2d at 1563–64, 19 USPQ2d at 1116–17, although we have also clarified that the possession test alone is not always sufficient to meet the written description requirement, *Enzo Biochem, Inc. v. Gen–Probe Inc.,* 285 F.3d 1013, 1020–21 (Fed.Cir.2002). As such, "the written description requirement is satisfied by the patentee's disclosure of 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.' " *Enzo Biochem,* 285 F.3d at 1021 (quoting *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed.Cir.1997)). Put another way, one skilled in the art, reading the original disclosure, must reasonably discern the limitation at issue in the claims. *Waldemar Link, GmbH & Co. v. Osteonics Corp.,* 32 F.3d 556, 558, 31 USPQ2d 1855, 1857 (Fed.Cir.1994).

[14] Whether a claim is enabled under 35 U.S.C. § 112, first paragraph is a question of law, although based upon underlying factual findings. See *PPG Indus., Inc. v. Guardian Indus. Corp.,* 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed.Cir.1996); *In re Goodman,* 11 F.3d 1046, 1049–50, 29 USPQ2d 2010, 2013 (Fed.Cir.1993).

III. DISCUSSION

A. The '511 Patent

On appeal, Crown describes various purported errors in the district court's analysis ***1377** of the validity of the '511 patent. Despite Crown's contentions, we ascertain no error requiring reversal of the district court's determination of validity over Crown's claims of anticipation and obviousness.

[15] [16] Regarding alleged anticipation by the Gillery patent, on its face the Gillery patent does not disclose or discuss a two percent limitation for the reflectance contribution of the solar control film. Crown maintains that the '511 patent merely claims a preexisting property inherent in the structure disclosed in the prior art. Crown urges us to accept the proposition that if a prior art reference discloses the same structure as claimed by a patent, the resulting property, in this case, two percent solar control film reflectance, should be assumed. We decline to adopt this approach because this proposition is not in accordance with our cases on inherency. If the two percent reflectance limitation is inherently disclosed by the Gillery patent,[2] it must be necessarily present and a person of ordinary skill in the art would recognize its presence. *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950–51 (Fed.Cir.1999); *Continental Can,* 948 F.2d at 1268, 20 USPQ2d at 1749. Inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* at 1269, 20 USPQ2d at 1749 (quoting *In re Oelrich,* 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981)).

[2] In order to claim "equivalent structure" between the Gillery patent and the '511 patent, Crown's inherency argument rests on a precondition of its own making—that the Gillery patent discloses use of TiO_2, even though it specifies TiO_x, where × is greater than 1.0 but less than 2.0. Although Crown vigorously argues this point, we do not reach this issue because even if Crown is correct that the structures are equivalent, Crown's inherency argument fails for the reasons set forth

herein.

[17] [18] In arguing inherent disclosure of the two percent limitation in the Gillery patent, Crown bears an evidentiary burden to establish that the limitation was necessarily present.[3] The moving party in a summary judgment motion has the burden to show "that there is an absence of evidence to support the non-moving party's case;" the non-moving party must affirmatively demonstrate by specific factual allegations that a genuine issue of material fact exists for trial. *Celotex Corp. v. Catrett,* 477 U.S. 317, 322–23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). A patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through clear and convincing evidence, *see United States Surgical Corp. v. Ethicon, Inc.,* 103 F.3d 1554, 1563, 41 USPQ2d 1225, 1232 (Fed.Cir.1997). Given the presumption of validity afforded the '511 patent, Crown has failed to meet its burden because it has not presented sufficient evidence to rebut the facial evidence offered by Solutia that the Gillery patent does not ***1378** disclose the two percent limitation. *See Eli Lilly & Co. v. Barr Lab. Inc.,* 251 F.3d 955, 962, 58 USPQ2d 1869, 1874 (Fed.Cir.2001) ("[A] moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent."); *In re Robertson,* 169 F.3d at 745 (recognizing that extrinsic evidence may be required to establish inherency). Instead, Crown offers only an assumption and its own contentions.[4]

[3] Crown's reliance on *Pall Corp. v. Micron Separations, Inc.,* 66 F.3d 1211, 36 USPQ2d 1225 (Fed.Cir.1995), and *O.I. Corp. v. Tekmar Co.,* 115 F.3d 1576, 42 USPQ2d 1777 (Fed.Cir.1997), to characterize the two percent limitation as a "performance limitation" similar to the claim terms at issue in those cases is unpersuasive and overbroad. Respectively, *Pall* and *Tekmar* dealt with the claim terms "skinless" and "passage." Beyond the readily apparent difference between these potentially broad terms and the precise specification of a two percent limit in the '511 patent, characterizing a claim limitation as a "performance characteristic" is not helpful as to whether the "necessarily present" requirement of inherency is met.

[4] As indicated by this Court's questions at oral argument concerning the seemingly direct route to prove that the Gillery patent contains the two percent limitation implementing an embodiment of the Gillery patent and testing it this Court finds puzzling Crown's reluctance regarding this approach to generate extrinsic proof that the Gillery patent inherently meets the two percent limitation.

Crown also argues that the district court erred by comparing reflectance values in the Gillery patent to non-corresponding values in the '511 patent. *August 22 Order* at 23–24. While perhaps the district court could have been more careful to explain the basis of its comparison, on a close reading of the district court's analysis we find that the alleged improper comparison only supported the district court's primary point that no embodiment of the Gillery patent disclosed the two percent limitation, a conclusion that Crown has not shown to be in error.

[19] Finally, Crown argues that various prior art references invalidate the '511 patent as obvious in view of such prior art. Crown's arguments lack merit because it has not shown that the prior art contains a teaching, suggestion or motivation to reduce the reflectance contribution of the solar control film to "no more than about two percent," and the district court properly concluded that there was no such teaching, suggestion or motivation in the prior art cited by Crown. *See Ruiz,* 234 F.3d at 665, 57 USPQ2d at 1167; *In re Rouffet,* 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed.Cir.1998).

B. The '258 Patent

On appeal, Crown argues that the district court erred in analyzing the impact of the ambiguities in the wave index calculation on the enablement requirement for the '258 patent. In addition to its enablement attack, Crown also argues that the '258 patent does not meet the written description requirement of § 112, first paragraph.

[20] [21] [22] The two requirements, while related and springing from the same factual predicates,[5] each carry a separate purpose. The purpose of the enablement requirement is to "ensure[ ] that the public ***1379** knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Nat'l Recovery Techs., Inc. v. Magnetic*

Separation Sys., 166 F.3d 1190, 1196, 49 USPQ2d 1671, 1675 (Fed.Cir.1999). One of our predecessor courts has held the enablement and written description requirements to be separate and distinct, and has held that a "specification may contain a disclosure that is sufficient to enable one skilled in the art to make and use the invention and yet fail to comply with the description of the invention requirement." *In re Barker and Pehl,* 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977). Subsequently, this court has held that the purpose of the written description is distinct from merely explaining how to make and use the invention. *See Enzo Biochem,* 285 F.3d at 1020–22; *Vas–Cath,* 935 F.2d at 1563–64, 19 USPQ2d at 1117. In light of the odd procedural setting of the written description issue in this appeal, our disposition of this appeal based on enablement, and given that the two requirements are distinct and each are necessary, we do not reach the written description issue except to note that it appears to remain available for adjudication or disposition by the district court on remand.[6]

[5] Also springing from these same underlying factual predicates is the § 112, second paragraph, definiteness requirement. This requirement is distinct from the enablement and description requirements, which arise from § 112, first paragraph.

> [D]efiniteness and enablement are analytically distinct requirements, even though both concepts are contained in 35 U.S.C. § 112. The definiteness requirement of 35 U.S.C. § 112, ¶ 2 is a legal requirement, based on the court's role as construer of patent claims ... Definiteness requires the language of the claim to set forth clearly the domain over which the applicant seeks exclusive rights.... The test for whether a claim meets the definiteness requirement is "whether one skilled in the art would understand the bounds of the claim when read in light of the specification."

Process Control Corp., 190 F.3d at 1358 n. 2, 52 USPQ2d at 1034 n. 2 (internal citations omitted). *See also* 3 Donald S. Chisum, Chisum on Patents, § 8.03 at 8–14 (2001) (noting the difference between the requirements of "definiteness, which claims must meet, from the requirements of enablement, which the disclosures of the specification must meet").

[6] Based on the record before us, the written description issue has the following procedural posture: (i) Crown's Count VI of its amended complaint raised the written description issue; (ii) Solutia's summary judgment motion argued that the '258 patent met the written description requirement; (iii) in opposition Crown argued that the written description requirement was not met; (iv) the district court did not dispose of the written description issue or discuss the issue in its opinion in a way that enables our review; and (v) Crown preserved the written description issue in its appeal to this court and thus has not waived its further adjudication on remand.

[23] Turning to the enablement issue, we agree with Crown that the ambiguities and lack of specified boundary conditions, and Crown's proffered evidence concerning the same, raise a genuine issue of material fact as to whether a person of ordinary skill in the pertinent art could make or use the invention of the '258 patent[7] without undue experimentation. *White Consol. Indus. v. Vega Servo–Control,* 713 F.2d 788, 791, 218 USPQ 961, 963–64 (Fed.Cir.1983). The district court found otherwise. However, it appears not to have considered the statements of Crown's expert concerning the effect of unspecified boundary conditions on the calculation of wave index.

[7] All seventeen claims of the '258 patent refer to wave index, thus they all stand or fall together.

Following the reasoning of the district court, Solutia argues that a person of ordinary skill in the pertinent art could overcome any ambiguities in the wave index calculation without undue experimentation by testing a limited number of possibilities for computing the wave index. In response, Crown offers statements of its expert that the '258 patent does not define amplitude and that a person of ordinary skill in the art would not know whether to measure amplitude: (i) from a centerline running horizontally through the "middle" of the trace; (ii) from "peak-to-peak," *i.e.,* from the bottom of a valley to the top of a peak; or (iii) from some other baseline or reference running horizontally somewhere through the trace. On its face, the '258 patent does not define amplitude. However, average amplitude directly impacts the wave index calculation because wave index ***1380** is the result of multiplying average amplitude by average pitch. Simply put, the wave index calculation would produce two separate numbers if calculated with a centerline versus a "peak-to-peak" amplitude. Worse yet, a range of various wave index values are possible for amplitude baselines running horizontally somewhere through the trace at various locations. To show that the wave index calculation is enabled, Solutia cites various details from

the '258 patent concerning how to perform the test to generate a trace of the PVB surface to calculate wave index. However, Solutia does not present sufficient evidence to rebut Crown's demonstration of the amplitude ambiguity in the wave index calculation. This is so because: (i) the amplitude is a direct input to the critical claim limitation, a wave index of less than 15,000 square micrometers; and (ii) the novel aspects of the invention must be disclosed and not left to inference, that is, a patentee may not rely on the inference of a person of ordinary skill in the pertinent art to supply such novel aspects. *See Genentech Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed.Cir.1997) (stating that the knowledge of a hypothetical person of ordinary skill in the art cannot be used to supply the patentable aspects of the invention).

Compounding the amplitude ambiguity, Crown also notes that the wave index is the result of two independently varying, unbounded terms: average pitch and average amplitude. On its face, this does not seem to be a problem. However, Crown's expert noted that because boundary conditions are not specified, the claim covers inoperative embodiments. For example, a wave index of 15,000 square micrometers results from an average height of 1000 micrometers multiplied by an average pitch of 15 micrometers. Yet, according to Crown's expert, an average height of 1000 micrometers would not be acceptable for the PVB. As with the amplitude ambiguity, the problem goes well beyond this single example because a full range of resulting inoperative embodiments are possible for values of average height and average pitch that, when multiplied, produce a wave index value that meets the limitation of the claim. Such inoperative embodiments do not necessarily invalidate the claim. *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.,* 750 F.2d 1569, 1576–77, 224 USPQ 409, 414 (Fed.Cir.1984); *In re Cook,* 58 C.C.P.A. 1049, 439 F.2d 730, 735, 169 USPQ 298, 302 (1971) (noting that although claims may read on some inoperative embodiments, this does not necessarily invalidate the claim if the necessary information to limit the claims to operative embodiments is known to a person of ordinary skill in the art).[8] However, the inoperative embodiments support Crown's assertion that there is a genuine issue of material fact with respect to enablement. *See Atlas Powder,* 750 F.2d at 1576–77; *see also Process Control Corp. v. HydReclaim Corp.,* 190 F.3d 1350, 1358–59, 52 USPQ2d 1029, 1034–35 (Fed.Cir.1999) (holding that the district court failed in its ***1381** claim construction to consider the effect of inoperative embodiments on invalidity due to lack of enablement).[9]

[8] The court in *In re Cook* further notes that a claim may be invalid if it reads on significant numbers of inoperative embodiments. *In re Cook,* 439 F.2d at 734, 169 USPQ at 301–02 (citing *Graver Tank & Mfg. Co. v. Linde Air Products Co.,* 336 U.S. 271, 276–77, 69 S.Ct. 535, 93 L.Ed. 672, 80 USPQ 451, 453 (1949)). *See also In re Moore,* 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971) (noting that the question is whether the scope of enablement conveyed by the disclosure to a person of ordinary skill in the art is commensurate with the scope of protection taught by the claims); Chisum, § 7.03[7][a] at 7–108 & n. 6.

[9] The inoperative embodiment inquiry informs the enablement inquiry; they are not the same inquiry. *Nat'l Recovery Techs.,* 166 F.3d at 1196, 49 USPQ2d at 1676.

Further compounding the ambiguities with the wave index rules, the ' 258 patent's rules for determining which inflection points are "true" inflection points additionally support Crown's argument that it has raised a genuine issue of material fact. Crown demonstrated in various ways through its experts and arguments the potential indeterminacy in the rules. Solutia's expert admitted that there was some ambiguity in the rules with respect to whether a preceding peak or valley was the reference point in selecting a "true" peak or valley.

Solutia argues that even if the disclosed wave index calculation has ambiguities and is indeterminate, a person of ordinary skill in the pertinent art would be able to make and use the invention with some experimentation, but less than "undue" experimentation. Solutia argues that such a skilled person would only have to try two possibilities for amplitude, centerline and "peak-to-peak," and that experimenting to discover which of two possibilities to use is well within the boundary of undue experimentation. Crown counters that the amplitude ambiguity and potential inoperative embodiments, combined with the ambiguities in the smoothing rules, seems to suggest a wide range of possibilities which one must try.[10] With this wide range of possibilities, we agree that Crown has raised a genuine issue of material fact as to the amount and type of experimentation required, facts that will determine whether such experimentation is undue. *See Enzo Biochem Inc., v. Calgene Inc.,* 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135–36 (Fed.Cir.1999) (holding that a reasonable amount of experimentation does not invalidate a patent, but undue experimentation does invalidate, and holding that the *Wands* factors, which determine whether

a patent's disclosure is insufficient such that the experimentation required would be undue, apply to inter partes litigation).[11] While ultimately a trier of fact may reach the conclusion that any required experimentation is not undue, Crown has shown that sufficient potential for undue experimentation exists such that disposal on summary judgment is improper.

[10] We note that the specification for the '258 patent states that in the disclosed embodiment the wave index is calculated using a software program running on a personal computer being fed the trace line. '258 patent, col. 7, ll. 64–68. Undoubtedly, Solutia took care to ensure that the program contained the necessary boundary conditions and other information to calculate wave index to practice the invention. It appears, however, that Solutia took substantially less care in transcribing the information from the program into the specification's rules for calculating wave index. This incongruity will be relevant to the question of enablement upon remand. *See* Chisum, § 7.03[4][e] at 7–86 & n. 77 ("A specification that claims an invention requiring implementation through computer software but fails to set forth the details of computer programming may present issues of whether the experimentation required to write the programming is reasonable or unreasonable.") (summarizing the teachings of various cases).

[11] The *Wands* factors are:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988).

***1382** CONCLUSION

Because we hold that the '511 patent has not been shown to be invalid due to anticipation or obviousness and that a genuine issue of material fact exists with respect to facts underlying the determination of enablement for the ' 258 patent, we affirm-in-part and reverse-in-part the district court's decision and remand for additional proceedings consistent with this opinion.

AFFIRMED–IN–PART, REVERSED–IN–PART, AND REMANDED.

COSTS

Each party bears its own costs.

All Citations

289 F.3d 1367, 62 U.S.P.Q.2d 1917

End of Document

723 F.3d 1336
United States Court of Appeals, Federal Circuit.

NOVOZYMES A/S, and Novozymes North America, Inc., Plaintiffs–Appellants,
v.
DuPONT NUTRITION BIOSCIENCES APS (formerly Danisco A/S), Genencor International Wisconsin, Inc., Danisco U.S. Inc., and Danisco USA Inc., Defendants–Appellees.

No. 2012–1433
|
July 22, 2013.
|
Rehearing En Banc Denied Oct. 23, 2013.*

* Circuit Judge Hughes did not participate.

Synopsis
Background: Owner of patent claiming particular modified enzymes that exhibit improved function and stability under certain conditions brought infringement action against competitor. Competitor counterclaimed seeking a declaratory judgment that claims were invalid for failing to satisfy the enablement and written description requirements. Following jury trial, the United States District Court for the Western District of Wisconsin, Barbara B. Crabb, Senior District Judge, granted competitor's post-trial motion for judgment as a matter of law that claims were invalid for failure to satisfy the written description requirement. Patent owner appealed.

[Holding:] The Court of Appeals, Schall, Circuit Judge, held that claims in patent were invalid for failure to meet written description requirement.

Affirmed.

Rader, Chief Judge, filed a dissenting opinion.

Procedural Posture(s): On Appeal; Motion for Judgment as a Matter of Law (JMOL)/Directed Verdict.

West Headnotes (11)

[1] **Federal Courts**🔑Taking case or question from jury; judgment as a matter of law

170BFederal Courts
170BXVIICourts of Appeals
170BXVII(K)Scope and Extent of Review
170BXVII(K)3Presumptions
170Bk3672Taking case or question from jury; judgment as a matter of law
(Formerly 170Bk801)

The Seventh Circuit reviews a district court's grant of a judgment as a matter of law motion without deference, while viewing all the evidence in the light most favorable to the nonmoving party. Fed.Rules Civ.Proc.Rule 50(a)(1), 28 U.S.C.A.

[2] **Patents**🔑Possession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention
(Formerly 291k99)

To satisfy the written description requirement, the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention, and demonstrate that by disclosure in the specification of the patent. 35 U.S.C.(2006 Ed.) § 112.

7 Cases that cite this headnote

[3] **Patents**🔑Amendment of Application

291Patents
291IVPatent Applications and Proceedings
291IV(B)Examination
291k946Amendment of Application
291k947In general

(Formerly 291k110)

Patent claims added during prosecution must find support sufficient to satisfy written description requirement in the written description of the original priority application. 35 U.S.C.(2006 Ed.) § 112.

31 Cases that cite this headnote

[4] **Patents** Written Description Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)

When determining whether patent meets written description requirement, assessing possession of the invention as shown in the disclosure requires an objective inquiry into the four corners of the patent specification. 35 U.S.C.(2006 Ed.) § 112.

8 Cases that cite this headnote

[5] **Patents** Disclosure as directed to one skilled in the art
Patents Possession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(2)Disclosure as directed to one skilled in the art
(Formerly 291k99)
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention
(Formerly 291k99)

The patent specification must describe an invention understandable to a skilled artisan and show that the inventor actually invented the invention claimed. 35 U.S.C.(2006 Ed.) § 112.

12 Cases that cite this headnote

[6] **Patents** Written Description Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)

A mere wish or plan for obtaining the claimed invention does not satisfy the written description requirement. 35 U.S.C.(2006 Ed.) § 112.

14 Cases that cite this headnote

[7] **Patents** Questions of law or fact

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(10)Questions of law or fact
(Formerly 291k314(5))

The written description inquiry presents an issue of fact. 35 U.S.C.(2006 Ed.) § 112.

4 Cases that cite this headnote

[8] **Patents** Particular products or processes

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(6)Particular products or processes
(Formerly 291k99)

Prior application failed to demonstrate to one of ordinary skill in art that, by application's filing date, patent owner had invented particular alpha-amylase variants that owner claimed almost a decade later in patent claiming particular modified enzymes that exhibit improved function and stability under certain conditions, and thus claims in patent were invalid for failure to meet written description requirement; while application provided formal textual support for each individual limitation recited in claims of patent, it nowhere described actual functioning, thermostable alpha-amylase variants that those limitations together defined, application contained no disclosure of any variant that actually satisfied claims, and lacked any indication that patent owner had invented any thermostable alpha-amylase variants substituted at amino acid position 239 by the time of filing, much less one specifically produced from a B. stearothermophilus (BSG) parent, as disclosed in patent. 35 U.S.C.(2006 Ed.) § 112.

9 Cases that cite this headnote

[9] **Patents** Patents
Patents Written Description Requirement

291Patents
291IIn General
291k401In general
(Formerly 291k1)
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
(Formerly 291k99)

A patent is not a reward for the search, but compensation for its successful conclusion; for that reason, the written description requirement prohibits a patentee from leaving it to the industry to complete an unfinished invention. 35 U.S.C.(2006 Ed.) § 112.

7 Cases that cite this headnote

[10] **Patents** In general; utility

291Patents
291XPatents Enumerated
291k2091In general; utility
(Formerly 291k328(2))

US Patent 7,541,026. Cited.

1 Case that cites this headnote

[11] **Patents** In general; utility

291Patents
291XPatents Enumerated
291k2091In general; utility
(Formerly 291k328(2))

US Patent 7,713,723. Invalid.

Attorneys and Law Firms

***1337** David K. Tellekson, Fenwick & West, LLP, of Seattle, WA, argued for plaintiffs-appellants. With him on the brief were Virginia K. DeMarchi, Melanie L. Mayer, Jeffrey V. Lasker, and Ewa M. Davison. Of counsel was Brian D. Buckley.

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Before RADER, Chief Judge, SCHALL and BRYSON, Circuit Judges.

Opinion for the court filed by Circuit Judge SCHALL.

Dissenting opinion filed by Chief Judge RADER.

Opinion

SCHALL, Circuit Judge.

Plaintiffs–Appellants Novozymes A/S and Novozymes North America, Inc. (collectively, ***1338** "Novozymes") and Defendants–Appellees DuPont Nutrition Biosciences APS, Genencor International Wisconsin, Inc., Danisco U.S. Inc., and Danisco USA Inc. (collectively, "DuPont") are competitors in the market for enzyme preparations used in a variety of commercial applications, including ethanol production. On May 11, 2010, Novozymes brought suit against DuPont in the Western District of Wisconsin, alleging infringement of its U.S. Patent No. 7,713,723 (the "'723 patent"). The '23 patent claims particular modified enzymes that exhibit improved function and stability under certain conditions. DuPont defended on grounds of noninfringement and invalidity and filed counterclaims seeking a declaratory judgment that the claims of the '23 patent are invalid for failing to satisfy the enablement and written description requirements of 35 U.S.C. § 112.

As litigation progressed, the parties filed several motions for summary judgment. In pertinent part, the district court granted summary judgment in favor of Novozymes on the issue of infringement and denied DuPont's motion for summary judgment of invalidity under the written description and enablement requirements. The case then went to trial before a jury, which concluded that the '23 patent's claims are not invalid on enablement or written description grounds and which awarded infringement damages to Novozymes exceeding $18 million. The district court, however, granted DuPont's post-trial motion for judgment as a matter of law that the claims of the '23 patent are invalid under § 112 for failure to satisfy the written description requirement.

Novozymes now appeals from the district court's final judgment of invalidity. For the reasons set forth below, we affirm.

BACKGROUND

I. Alpha–Amylase Enzymes

The '23 patent, entitled "Alpha–Amylase Mutants with Altered Properties," relates to recombinant enzyme technology. Enzymes are proteins that catalyze biochemical reactions, that is, they facilitate molecular processes that either would not occur or would occur much more slowly in the enzyme's absence. Living cells produce different enzymes to carry out a vast array of metabolic functions. For example, one enzyme might help to join the molecular building blocks needed to make a new DNA molecule, while another might break a complex molecule, such as a carbohydrate, into useful constituent parts.

Like all proteins, enzymes are composed of amino acid molecules linked together to form a continuous chain. An enzyme's primary structure is defined by the sequence of amino acid molecules in the chain; in general, each individual position in the amino acid sequence can consist of any one of twenty amino acids normally found in nature. In addition, the linear amino acid chains of different enzymes will bend, fold, and loop onto themselves to assume characteristic three-dimensional confirmations. Both the primary amino acid sequence and the three-dimensional structure affect an enzyme's ultimate functional properties.

Alpha-amylases constitute a class of enzymes synthesized by a variety of organisms—from bacteria to fungi to humans—that break down large molecules known as polysaccharides. Polysaccharides, such as starch and glycogen, are defined as long-chain polymers made of repeating simple sugar molecules like glucose, among others. Alpha-amylases sever the bonds between adjacent sugars in a polysaccharide to yield single or short-chain simple sugars that can provide energy or be used as building blocks for other cellular processes. ***1339** On average, alpha-amylase enzymes comprise approximately 500 amino acids.

Beyond a widespread role in natural systems, alpha-amylases also have important commercial applications in detergent formulations, sugar refining, and ethanol production, among other uses. Of particular note, many alpha-amylases derived from bacteria of the genus *Bacillus* exhibit exceptional enzymatic activity, which has made those bacterial enzymes attractive for commercial use. One such product is a preparation of alpha-amylase derived from *B. licheniformis* ("BLA") that Novozymes markets under the name Termamyl0.

II. Novozymes's 2000 Patent Application

Many of the most common commercial or industrial

applications for alpha-amylase enzymes involve harsh conditions, including high temperatures and/or high acidity. Exposure to such conditions progressively destabilizes and deactivates natural *Bacillus* alpha-amylase enzymes, degrading the performance of the associated enzyme-based products or processes over time. In the late 1990s, Novozymes sought to improve the acid tolerance and heat tolerance ("thermostability") of *Bacillus* alpha-amylases used in commercial processes.

Traditionally, the solution had been to add excess calcium to commercial alpha-amylase formulations intended for use under extreme temperature or pH conditions. While concentrated calcium is effective for stabilizing alpha-amylases to preserve their enzymatic activity, it represents an added cost and often imposes undesirable effects on industrial equipment. Thus, Novozymes's aim was to modify a naturally occurring "parent" *Bacillus* alpha-amylase to produce an enzyme having improved stability and thus more durable activity under harsh conditions, even without calcium supplementation.

Enzymes can often be altered at one or more positions along their amino acid chain without destroying their function. Changes (known as "mutations") in a parent enzyme can include deleting one or more amino acids, adding one or more amino acids, or substituting the original amino acid with one of the nineteen other possibilities at any given position in the sequence. An enzyme that has one or more mutations relative to its natural parent sequence is referred to as a "variant." The effects of any given mutation or combination of mutations in a variant can differ depending on the position(s) modified and the specific mutation implemented at each position. Some mutations may have no discernible effect on enzyme function, some may lead to varying degrees of instability or functional impairment, and some may actually improve enzyme activity or impart other desirable properties, such as improved stability at high temperatures.

Novozymes pursued two parallel strategies in attempting to identify promising mutation sites among the approximately 500 amino acids that make up a *Bacillus* alpha-amylase polypeptide: rational protein design and random mutagenesis. Rational protein design involves making functional inferences from the amino acid sequence and three-dimensional shape of a protein to predict which positions may influence a property of interest, such as thermostability, enzymatic activity, or calcium binding. In contrast, random mutagenesis involves making random mutations in a parent enzyme and then screening the resulting variants to identify those that exhibit the desired functional effects. Using rational protein design and random mutagenesis, Novozymes identified thirty-three *Bacillus* alpha-amylase amino acid positions as targets for mutation in attempting to create alpha-amylase variants with enhanced stability. Of those thirty-three positions, seventeen were predicted using rational protein design techniques, ***1340** while sixteen were identified via random mutagenesis experiments.

With that information in hand, Novozymes filed U.S. Provisional Patent Application No. 60/249,104 on November 16, 2000 (the "2000 application"), relating to *Bacillus* alpha-amylase variants with enhanced stability.[1] The 2000 application disclosed seven potential parent enzymes, including an alpha-amylase isolated from BLA bacteria that Novozymes was already using in its Termamyl0 product, and another alpha-amylase produced by *B. stearothermophilus* ("BSG"). *See* '23 patent col. 3 ll. 1–38. The 2000 application also disclosed the thirty-three separate amino acid positions along the alpha-amylase chain that Novozymes identified as promising mutation targets using rational protein design or random mutagenesis. In addition, the specification indicated that one or more of those sites might be altered in any of the seven disclosed parent alpha-amylases by deletion, addition, or substitution. *See id.* col. 7 ll. 36–57. The 2000 application further indicated that the disclosed variants would exhibit improved stability at "high temperatures (i.e., 70–120°C.) and/or extreme pH (i.e., low or high pH, i.e., pH 4–6 or pH 8–11), in particular at free (i.e., unbound, therefore in solution) calcium concentrations below 60 ppm." *See id.* col. 16 ll. 42–47.

[1] The written descriptions of the 2000 application and the '23 patent are nearly identical. For convenience, we will cite portions of the '23 patent when referencing identical, corresponding disclosures in the 2000 application.

Given the number of parent enzymes (7), the number of target positions in each of those parent enzymes (33), and the number of possible mutations at each of those target positions (at least 40),[2] the disclosure in the 2000 application spans a potentially wide range of alpha-amylase variants. For example, one of the seventeen positions identified by rational protein design was position 239, occupied by the amino acid serine (abbreviated as "S") in the disclosed parent alpha-amylase proteins. Many mutations would be possible at position 239, such as an enumerated variant that would require replacing the original serine with the amino acid tryptophan (abbreviated as "W")—a substitution mutation that can be expressed as "S239W." *See id.* col. 8 l. 12. The 2000 application includes pages of similar exemplary substitutions, presented alone and in double, triple, or

larger combinations, but the application does not state that any one of the thirty-three disclosed mutations sites is preferred over any other and does not state whether single or combined mutations are preferred. *See id.* col. 8 l. 25–col. 16 l. 37.

[2] According to the 2000 application, the possible mutations at any amino acid position would include a single deletion, a substitution with any of the 19 other amino acids, and a single downstream addition of any of the 20 amino acids. *See* '23 patent col. 7 ll. 45–52.

Finally, the 2000 application provided two examples with empirical data confirming the enhanced stability of selected variants harboring mutations at the sixteen positions that were identified through random mutagenesis. *See id.* col. 25 l. 1–col. 26 l. 65. No such data were disclosed regarding the activity or thermostability of any of the seventeen positions that had been identified through rational protein design, however. Indeed, later experiments revealed that some of the seventeen predicted positions did not yield *any* thermostable variants, and even for many of those that did, only a minority of substitutions actually had the desired effect. For example, no substitutions at predicted positions 179 or 180 actually led to increased thermostability, and thirteen of the nineteen possible substitutions at position 239 ***1341** proved similarly ineffective, including the disclosed S239W mutation.

Novozymes filed its first non-provisional patent application claiming priority from the 2000 application on July 31, 2001. After the examiner issued a restriction requirement directing Novozymes to elect a single disclosed species, i.e., a single specific parent alpha-amylase with a single specific amino acid substitution, Novozymes elected a BLA parent modified at position 49. In addition, Novozymes filed a continuation application on July 29, 2003, electing a BLA parent modified at position 170. Neither of those applications resulted in an issued patent.

III. DuPont's Accused Products and the '23 Patent

In 2006, while Novozymes's patent prosecution efforts remained ongoing, DuPont began work to develop an alpha-amylase having increased stability at high temperatures and low calcium concentrations for use in corn ethanol production. Starting from a BSG parent enzyme that corresponded to one of its own existing alpha-amylase products, DuPont produced approximately 1,500 alpha-amylase variants with substitutions covering 150 of the 515 amino acid positions in the parent BSG enzyme. Of those 150 positions, six also appeared in the list of thirty-three candidate positions disclosed in Novozymes's 2000 application. DuPont then screened its panel of 1,500 variants for increased thermostability under low-calcium conditions and identified a variant substituted at position 239 as the best performer. As described, position 239 was also among the thirty-three positions disclosed in Novozymes's 2000 application, though the particular substitution DuPont chose—replacing serine 239 with glutamine ("Q"), denoted "S239Q"—was not. In November 2008, DuPont filed a patent application and developed a new thermostable alpha-amylase product based on the BSG S239Q variant. DuPont's patent application issued as U.S. Patent No. 7,541,026 in June 2009.

Upon learning that DuPont had introduced a thermostable BSG alpha-amylase variant substituted at position 239, Novozymes filed a new continuation application on December 22, 2009, (the "2009 application") that claimed priority from its original 2000 application. The written descriptions of the 2009 application and the 2000 application were nearly identical, but Novozymes for the first time sought claims drawn specifically to BSG alpha-amylase variants substituted at position 239. The '23 patent issued from the 2009 application on May 11, 2010, with seventeen claims. Claim 1 is representative:

> 1. An isolated variant of a parent alpha-amylase, wherein:
>
> (a) the variant has at least 90% sequence identity to SEQ ID NO: 6 [BSG alpha-amylase],
>
> (b) the variant *comprises a substitution of serine at position 239* relative to the parent alpha-amylase, using the amino acid sequence of SEQ ID NO: 8 [BLA alpha-amylase] for determining position numbering, and
>
> (c) the variant has increased thermostability relative to the parent alpha-amylase, wherein thermostability is determined at pH 4.5, 90° C. and 5 ppm calcium and has alpha-amylase activity.

'23 patent col. 87 ll. 40–51 (emphasis added). Like claim 1, all claims of the '23 patent require an alpha-amylase variant with at least the following three features: (1) a parent sequence having at least 90% homology with BSG alpha-amylase; (2) a substitution at position S239; and (3) increased thermostability at 90°C, pH 4.5, and 5 ppm calcium. Each of those limitations can be found at points

within the underlying 2000 application, but, outside of ***1342** the '23 patent's claims, Novozymes never presented them together in any particular embodiment and did not highlight the BSG parent or position 239 among the other disclosed options.

IV. District Court Proceedings

On May 11, 2010, the same day the '23 patent issued, Novozymes filed a complaint in the Western District of Wisconsin accusing DuPont of infringing claims 1–5, 8–13, and 15–16 of the '23 patent. DuPont's answer included noninfringement and invalidity defenses, as well as counterclaims for invalidity under the enablement and written description requirements of § 112, ¶ 1.[3] Shortly thereafter, the district court denied Novozymes's motion for a preliminary injunction, in part because, in its view, DuPont's written description challenge had raised a substantial question regarding the validity of the '23 patent's claims. *Novozymes A/S v. Danisco A/S,* No. 10–cv–251, 2010 WL 3783682, at *5 (W.D.Wis. Sept. 24, 2010) ("[A] substantial question remains whether [the] '23 patent will survive defendants' challenge to the patent's validity.").

[3] Paragraph 1 of 35 U.S.C. § 112 was replaced with newly designated § 112(a) when § 4(c) of the Leahy–Smith America Invents Act ("AIA"), Pub.L. No. 112–29, took effect on September 16, 2012. Because this case was filed before that date, we will refer to the pre-AIA version of § 112.

On February 4, 2011, the district court denied DuPont's motion for summary judgment that the '23 patent was invalid for lack of written description. *Novozymes A/S v. Danisco A/S,* No. 10–cv–251 (W.D.Wis. Feb. 4, 2011), ECF No. 185 ("*Written Description Summary Judgment Order* "). The district court indicated that it "still [had] doubts that the specification of the '23 patent provides an adequate written description for the claims," *id.* at 2, but the court concluded that the parties' conflicting positions reflected at least a genuine issue of material fact. The district court later granted summary judgment in favor of Novozymes on the issue of infringement, holding that DuPont's products literally infringed the asserted claims of the '23 patent. *Novozymes A/S v. Danisco A/S,* No. 10–cv–251, slip op. at 4–30 (W. D.Wis. July 7, 2011), ECF No. 399.

The case then went to trial before a jury. DuPont maintained its validity challenges, asserting that the claimed subject matter was neither enabled nor sufficiently described in the 2000 application. At the trial's conclusion, the jury was provided a special verdict form that asked whether DuPont had "proven by clear and convincing evidence that any one or more of the ['23 patent's] claims are invalid because the application filed on November 16, 2000 ... does *not* contain an adequate written description," and, similarly, whether DuPont had established that the claims were not enabled. The jury answered "No" as to each claim. The jury further concluded that DuPont's adjudged infringement was willful and awarded Novozymes $18,219,500 in damages. Accordingly, the district court entered judgment for Novozymes on October 27, 2011.

After the entry of judgment, Novozymes sought a permanent injunction, fees, enhanced damages, and pre- and post-judgment interest, while DuPont filed motions for judgment as a matter of law on various issues, including willfulness, damages, and invalidity for lack of enablement and written description. In an order dated May 4, 2012, the district court granted DuPont's motion for judgment as a matter of law under Federal Rule of Civil Procedure 50(b), holding that the claims of the '23 patent were invalid under § 112 for lack of adequate written description in the 2000 application. ***1343** *Novozymes A/ S v. Danisco A/S,* No. 10–cv–251 (W.D.Wis. May 4, 2012), ECF No. 966 ("*JMOL Order* ").

Addressing the written description requirement, the district court stated that "[t]he concern is that a patentee may attempt to use later filed claims, relying on more recently discovered data, to expand the scope of his invention or to complete an idea." *Id.* at 6 (citing *Billups–Rothenberg, Inc. v. Associated Reg'l & Univ. Pathologists, Inc.,* 642 F.3d 1031, 1036 (Fed.Cir.2011)). Turning to the '23 patent, the court noted that the 2000 application disclosed a potentially enormous number of alpha-amylase variants, encompassing all possible combinations among the seven disclosed parent enzymes, the thirty-three disclosed positions for mutation, the numerous different mutations possible at each position, and the various possible combinations of individual mutations. The court also noted that the 2000 application did not point out the specific variants later claimed in the '23 patent. *Id.* at 6–7.

In its analysis, the district court analyzed precedents in which patent claims had been held invalid due to an underlying written description that set forth a broad, generic group of structures without specifically identifying the later-claimed species among many possible options. *Id.* at 9–12 (citing *Boston Scientific Corp. v. Johnson & Johnson,* 647 F.3d 1353

(Fed.Cir.2011); *Billups–Rothenberg,* 642 F.3d at 1036; *Centocor Ortho Biotech, Inc. v. Abbott Labs.,* 636 F.3d 1341 (Fed.Cir.2011); *Univ. of Rochester v. G.D. Searle & Co.,* 358 F.3d 916 (Fed.Cir.2004); *Purdue Pharma L.P. v. Faulding Inc.,* 230 F.3d 1320 (Fed.Cir.2000); *In re Ruschig,* 54 C.C.P.A. 1551, 379 F.2d 990 (1967)). Acknowledging that the '23 patent was "superficially different" from the patents at issue in those cases, in that the 2000 application expressly named the individual limitations recited in the claims, *id.* at 9–10, the district court nonetheless concluded that "there is no meaningful difference between identifying a generic group in which a limitation of a claim may be found (as in many of the prior cases) and individually listing each member of that group without directing the reader to a particular member (as in the '23 patent)." *Id.* at 11. In the district court's view, the problem in either situation was that "the specification failed to inform the reader which member of that group was the right one." *Id.* Accordingly, because "[t]he actual inventive work of producing a [working variant] was left for subsequent inventors to complete," the district court held that the 2000 application provided insufficient written description for the claims of the '23 patent and that those claims were therefore invalid under § 112. *Id.* at 17–18 (alterations in original) (quoting *Centocor,* 636 F.3d at 1353) (internal quotation marks omitted).

The district court thus granted DuPont's motion for judgment as a matter of law. *JMOL Order,* slip op. at 19. On May 11, 2012, the court entered an amended judgment in favor of DuPont, holding the claims of the '23 patent invalid for lack of sufficient written description under § 112, ¶ 1.[4]

[4] Having invalidated the claims of the '23 patent for lack of adequate written description, the district court dismissed the parties' other post-trial motions, including DuPont's parallel motion for judgment as a matter of law on the issue of enablement.

Novozymes filed a timely notice of appeal on May 29, 2012. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of Review

[1] When reviewing a district court's grant of judgment as a matter of law, we apply the law of the governing regional circuit. ***1344** *Uniloc USA, Inc. v. Microsoft Corp.,* 632 F.3d 1292, 1301 (Fed.Cir.2011). "The Seventh Circuit reviews a district court's grant of a JMOL motion without deference, while viewing all the evidence in the light most favorable to the nonmoving party." *Trading Techs. Int'l v. eSpeed, Inc.,* 595 F.3d 1340, 1357 (Fed.Cir.2010) (citing *Harper v. Albert,* 400 F.3d 1052, 1061 (7th Cir.2005)). Judgment as a matter of law "is proper when 'a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue.' " *Harper,* 400 F.3d at 1061 (quoting Fed.R.Civ.P. 50(a)(1)).

II. Issues Presented

A. The Written Description Requirement

The written description requirement is set forth in the first paragraph of 35 U.S.C. § 112. *Ariad Pharm., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336, 1343–45 (Fed.Cir.2010) (en banc). In pertinent part, § 112 provides that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1 (2006).

[2] [3] [4] [5] [6] [7] To satisfy the written description requirement, "the applicant must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate that by disclosure in the specification of the patent." *Carnegie Mellon Univ. v. Hoffmann–La Roche Inc.,* 541 F.3d 1115, 1122 (Fed.Cir.2008) (quoting *Vas–Cath Inc. v. Mahurkar,* 935 F.2d 1555, 1563–64

(Fed.Cir.1991)). Accordingly, claims added during prosecution must find support sufficient to satisfy § 112 in the written description of the original priority application. *See, e.g., Anascape, Ltd. v. Nintendo of Am., Inc.,* 601 F.3d 1333, 1335 (Fed.Cir.2010). Assessing "possession as shown in the disclosure" requires "an objective inquiry into the four corners of the specification." *Ariad,* 598 F.3d at 1351. Ultimately, "the specification must describe an invention understandable to [a] skilled artisan and show that the inventor actually invented the invention claimed." *Id.* A "mere wish or plan" for obtaining the claimed invention does not satisfy the written description requirement. *Regents of the Univ. of Cal. v. Eli Lilly & Co.,* 119 F.3d 1559, 1566 (Fed.Cir.1997). The written description inquiry presents an issue of fact. *Ariad,* 598 F.3d at 1351.

B. The Parties' Contentions

To begin, Novozymes argues that the level of skill in the art of alpha-amylase biotechnology is very high and that, at the time that the 2000 application was filed, a person of ordinary skill in that art would have recognized the field as well developed and predictable. Specifically, Novozymes contends that alpha-amylases have been studied since 1833 and that, by the time it filed the 2000 application, the amino acid sequences and three-dimensional structures of many alpha-amylases had been solved, methods for introducing mutations into alpha-amylase proteins and measuring the resulting variants' enzymatic activity were well known, and the use of alpha-amylase structure-function relationships in designing variants was commonplace and effective. Novozymes further argues that the key to deriving functional alpha-amylase variants lies in finding the right position to mutate rather than the specific mutation(s) made at that position.

***1345** In that context, Novozymes asserts that sufficient evidence supported the jury's validity determination, emphasizing that the 2000 application expressly discloses each limitation of the asserted claims, namely (1) a parent BSG alpha-amylase; (2) a substitution at the S239 position; and (3) increased thermostability at 90°C, pH 4.5, and 5 ppm calcium. In Novozymes's view, a person of ordinary skill in the art thus would have understood the 2000 application as clearly describing the claimed invention. Moreover, Novozymes argues that the district court revisited factual issues without applying the deferential standard demanded by Rule 50(b). In particular, Novozymes complains that the district court discounted its experts' testimony indicating that a person of ordinary skill in the art would have had no difficulty deriving the claimed invention from the disclosure of the 2000 application.

In addition, Novozymes distinguishes *Boston Scientific* and like cases on the grounds that those cases concerned complex, unpredictable technologies and involved written descriptions that lacked express disclosure of the claimed subject matter. Relying on *Snitzer v. Etzel,* 59 C.C.P.A. 1242, 465 F.2d 899 (1972), Novozymes argues that the 2000 application's written description is not deficient simply because it discloses unclaimed inventions and inoperative species. Novozymes also points to *Union Oil Co. of California v. Atlantic Richfield Co.,* 208 F.3d 989 (Fed.Cir.2000), as illustrating that the level of ordinary skill and predictability in an art inform the written description inquiry. According to Novozymes, *Union Oil* demonstrates that a disclosure is not lacking merely because it relies on the understanding of an ordinarily skilled reader.

For its part, DuPont defends the district court's judgment, arguing that the written description requirement precludes premature claims to a research plan and requires the disclosure of an actual invention. According to DuPont, Novozymes disclosed in its 2000 application no more than a theory or a laundry list of potential solutions, while DuPont performed the hard, inventive work of actually deriving a useful variant of BSG alpha-amylase.

Citing *In re Ruschig,* 54 C.C.P.A. 1551, 379 F.2d 990 (1967), DuPont argues that where a patentee adds claims during prosecution that, as here, were not included in the original priority application, courts require a detailed description and identification of the later-claimed invention in the original disclosure, particularly where the specification discloses numerous possibilities with scant guidance on which to select. In this case, DuPont points out that the 2000 application fails to disclose a single alpha-amylase variant substituted at position 239 that actually exhibits increased thermostability, noting that the only disclosed substitution at that position (S239W) disclosed in the 2000 application does not work as required by the '23 patent's claims. DuPont also asserts that the 2000 application's undifferentiated disclosure was no more than an "invitation to experiment" that failed to provide guidance toward the later-claimed solution.

Additionally, DuPont discounts *Union Oil* as conflating the written description requirement with "enablement reasoning," an approach that it claims is no longer viable in view of *Ariad.* DuPont also distinguishes *Union Oil* on the ground that the disclosure in that case taught exactly how to make compositions with the claimed properties,

while the disclosure of the 2000 application offers no insight as to how any given mutation at any of the disclosed amino acid positions would affect the functional properties of a resulting variant.

Finally, DuPont accuses Novozymes and its experts of relying on hindsight to work ***1346** backward from the claims of the '23 patent, filed in 2009, to show that, given knowledge of the claimed invention, each limitation could be retroactively derived from the disclosure of the 2000 application.

III. Analysis

A. Holding

In view of the record before us, including the disclosure of the 2000 application, we hold that no reasonable jury could find that the claims of the '23 patent meet the written description requirement of § 112, ¶ 1, and that the district court therefore correctly entered judgment as a matter of law invalidating those claims. In contrast to the claims—which narrowly recite specific alpha-amylase variants that result from mutating a particular parent enzyme at a single amino acid position to yield distinctive functional properties—the supporting disclosure of the 2000 application provides only generalized guidance listing several variables that might, in some combination, lead to a useful result. Taking the claims as a whole rather than as the sum of their individual limitations, nothing in the 2000 application indicates that Novozymes then possessed what it now claims. Finally, the testimony of Novozymes's experts does not overcome the fundamental deficiencies of the 2000 application's written description.

B. Legal Framework

Numerous prior decisions addressing the written description requirement guide our analysis in this case. We have consistently held that, to satisfy § 112, a patent's written description "must 'clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.' " *Ariad,* 598 F.3d at 1351 (alteration in original) (quoting *Vas–Cath,* 935 F.2d at 1563). A "mere wish or plan" to obtain the claimed invention is not sufficient. *Regents of the Univ. of Cal.,* 119 F.3d at 1566.

We have often applied those fundamental concepts to hold claims invalid in cases where a patent's written description disclosed certain subject matter in terms of a broad genus but its claims specified a particular subgenus or species contained therein. For example, in *Ruschig,* our predecessor court affirmed the holding of the Patent Office Board of Appeals that a claim to a specific drug molecule, added after filing, lacked sufficient description in the underlying application, which disclosed only a generic structure that could yield the claimed molecule given the proper selections at several variable positions. 379 F.2d at 993–94. In that case, the application's undifferentiated description was deficient because it failed to provide sufficient "blaze marks" to guide a reader through the forest of disclosed possibilities toward the claimed compound, which resided among the myriad others that also could have been made. *Id.* at 994–95.

We have reached similar conclusions in subsequent cases. For example, the claims at issue in *Boston Scientific* required drug-eluting stents incorporating a particular drug or a "macrocyclic triene analog" of that drug. 647 F.3d at 1367. The supporting written description disclosed a broad genus of "analogs" and made passing reference to the term "macrocyclic triene" but failed to describe or identify any member of the claimed sub-genus of macrocyclic triene analogs. *Id.* Because "nothing in the [disclosure] indicate[d] that the claimed triene analogs might be of special interest," and because the disclosure did not identify any such analogs or any reliable means for divining one, we held that the written description failed to demonstrate that the inventors were in possession of the claimed invention. *Id.* at 1367–69. In *Purdue Pharma,* ***1347** the disputed claims recited an extended-release drug formulation requiring a certain ratio between the drug's maximum blood concentration and its concentration at twenty-four hours after administration. 230 F.3d at 1323. The supporting disclosure included seven examples, two of which could be shown to meet the claimed ratio limitation by piecing together the disclosed data, but "neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasize[d] the [claimed] ratio." *Id.* at 1326. Accordingly, we upheld the district court's conclusion that "one of ordinary skill in the art would not be directed to the [claimed] ratio as an aspect of the invention." *Id.* Finally, in *University of Rochester,* we affirmed a summary judgment of invalidity for lack of written description because the claimed methods required administering a drug having a certain, selective activity, but the specification did not disclose any suitable drugs, and none were known in the art at the time of filing. 358 F.3d at 927. At most, the specification provided screening assays for identifying suitable drug

candidates. *Id.* We therefore held that the claims failed the written description requirement. We stated that the disclosure represented no more than a "wish or plan for obtaining the claimed chemical invention" and did "not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods." *Id.* at 927, 929.

On the other hand, in some cases, broad or generic disclosures can adequately describe particular constituent species. Thus, in *Snitzer,* our predecessor court held that claims requiring a specific laser-active ytterbium ion had been adequately described in an accompanying disclosure naming that ion among a group of fourteen individually enumerated ions that were described as useful separately or in various combinations. The written description challenge in that case cast the disclosure as speculative and misleading because several of the fourteen disclosed ions had proven to be inoperative. 465 F.2d at 902. The court nonetheless held that the literal description of the ytterbium ion provided adequate support for claiming that species, whether or not a larger group containing several inoperative species was also disclosed. *Id.* The court similarly held that certain species claims had been adequately described in *In re Driscoll,* 562 F.2d 1245 (CCPA 1977). In that case, the disputed claim recited a chemical compound having a specific substituent at one of several variable positions. *Id.* at 1246. The disclosure listed a number of possible structures that could be incorporated at the position in question, including one option that ultimately appeared in the claims. *Id.* at 1249. Again, the court held that the written description was sufficient because the particular claimed compound had been individually described as one of several possibilities. *Id.* at 1250.

In addition, in *Union Oil,* we affirmed a district court's finding that claims to gasoline compositions capable of reducing tailpipe emissions had adequate written description support. 208 F.3d at 996–1001. Rather than reciting a recipe of specific ingredients, the claims in that case defined the claimed gasoline compositions in terms of various chemical and physical properties. *Id.* at 992. The supporting specification disclosed that the properties recited in the claims correlated with emission levels, but the specification did not set forth specific compositions that would achieve those properties. *Id.* at 998–99. The record in the case, however, demonstrated that ordinarily skilled petroleum refiners would immediately appreciate that the qualitative chemical properties recited in the claims translated to specific, manifest compositions that would yield those properties. In other words, given the target properties, anyone having ordinary skill in the art of ***1348** petroleum refining would have been able to envision and readily produce a composition having those characteristics. The written description thus showed that "the inventors possessed the claimed invention at the time of filing in the assessment of those of ordinary skill in the petroleum refining art." *Id.* at 999.

C. The Present Case

[8] Turning to the case at hand, the question before us is whether the 2000 application demonstrates to one of ordinary skill in the art that, by the application's filing date, Novozymes had invented the particular alpha-amylase variants that Novozymes claimed almost a decade later in the '23 patent. We conclude that it does not.[5]

[5] Novozymes expends considerable effort emphasizing that the district court submitted the written description issue—an issue of fact—to the jury, which then found the claims not invalid. Novozymes thus appears to suggest that it was inherently inappropriate for the district court to overturn a jury verdict concerning the written description requirement. But a verdict on written description is no more immune from review than any other factual issue, and we have in past cases held that the entry of judgment as a matter of law on written description grounds was appropriate. *See, e.g., Centocor,* 636 F.3d at 1353 (holding claims invalid for inadequate written description and reversing the denial of a post-verdict motion for judgment as a matter of law); *Ariad,* 598 F.3d at 1340 (same).

As described, claim 1 of the '23 patent recites an alpha-amylase variant that (1) has at least 90% sequence identity to BSG alpha-amylase, (2) includes an amino acid substitution at serine 239, and (3) has increased thermostability at pH 4.5, 90°C, and 5 ppm calcium. '23 patent col. 87 ll. 40–50. Novozymes is correct that each of those individual limitations is expressly stated in the disclosure of the 2000 application. Specifically, the 2000 application (1) lists BSG as one of seven disclosed parent alpha-amylase enzymes, *see* '23 patent col. 3 ll. 1–50; (2) includes amino acid position 239 among a group of thirty-three positions that could be mutated to produce a variant alpha-amylase, *see id.* col. 7 ll. 36–58; and (3) states that the disclosed alpha-amylase variants should function at high temperatures ("especially 85–95° C"), low pH ("especially 4.5–5"), and at low calcium concentrations ("especially 5 ppm calcium"), *see id.* col. 7

l. 6–32; col. 16 ll. 42–47.

The 2000 application, however, contains no disclosure of any variant that actually satisfies the claims, nor is there anything to suggest that Novozymes actually possessed such a variant at the time of filing. First, the bulk of the specification focuses on using BLA (Termamyl0) alpha-amylase, rather than BSG alpha-amylase, as the parent enzyme. BLA alpha-amylase is described as the "preferred" parent in the 2000 application, *see* '23 patent col. 5 ll. 21–26, and appears in the two disclosed working examples.[6] BLA alpha-amylase, though, shares only 65.4% sequence identity with BSG alpha-amylase—i.e., less than the 90% identity required by the claims. *Id.* col. 3 ll. 6–20 (Table 1). In addition, amino acid position 239 is disclosed in the 2000 application as only one among a list of thirty-three positions that could be altered by deletion, insertion, or substitution, either alone or in combination. *See id.* col. 7 ll. 35–52. And while the bulk of the disclosure concerns substitutions, the only specifically ***1349** described substitution at position 239 is S239W, *see id.* col. 8 l. 12, which the parties agree *does not* confer increased thermostability in alpha-amylase enzymes and thus would fall outside of the claims.

[6] One of the few differences between the written description of the 2000 application and that of the later-filed '23 patent is that the 2000 application names only BLA alpha-amylase as a "preferred" parent enzyme, while language was added to the '23 patent denoting BSG alpha-amylase as another "preferred" option. '23 patent col. 21 ll. 47–50; *see also* Appellants' Br. 37 n. 7 (acknowledging that "[t]he November 2000 Application does not refer to BSG variants as preferred").

Nevertheless, the 2000 application's written description might superficially appear to differ from those exemplified in cases like *Ruschig* and *Boston Scientific,* where undifferentiated generic disclosures provided no description regarding the particulars of a claimed species, and to more closely resemble the written description in *Snitzer* or *Driscoll,* where claims to a specific member of a more broadly disclosed group were upheld because the claimed species had been literally described. In particular, BSG alpha-amylase, amino acid position 239, and improved thermostability—all recited as limitations in the claims of the '23 patent—are literally described in the disclosure of the 2000 application.

On closer examination, however, such analogies fall flat. While the 2000 application provides formal textual support for each individual limitation recited in the claims of the '23 patent, it nowhere describes the actual functioning, thermostable alpha-amylase variants that those limitations together define. Taking each claim—as we must—as an integrated whole rather than as a collection of independent limitations, one searches the 2000 application in vain for the disclosure of even a single species that falls within the claims or for any "blaze marks" that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities. "Working backward from a knowledge of [the claims], that is by hindsight," Novozymes seeks to derive written description support from an amalgam of disclosures plucked selectively from the 2000 application. *Ruschig,* 379 F.2d at 995. Indeed, Novozymes' expert, Dr. Arnold, in effect admitted that her testimony suffered from this flaw when she "point[ed] to [a] part of the claim" and told the judge she was "going back and finding if there's a written description for that" in the specification. With such an approach "it is all very clear what route one would travel through the forest of the specification to arrive at [the claimed invention]." *Ruschig,* 379 F.2d at 995. However, viewing the matter from the proper vantage point "of one with no foreknowledge of the specific compound," we agree with the district court that the particular variants claimed in the '23 patent lack meaningful support in the written description of the 2000 application. *Id.*

Furthermore, while the disclosure of an inoperative embodiment like the S239W substitution is not necessarily invalidating, *see Snitzer,* 465 F.2d at 902, the 2000 application lacks any indication that Novozymes had invented any thermostable alpha-amylase variants substituted at amino acid position 239 by the time of filing, much less one specifically produced from a BSG parent. The specification does provide examples showing that Novozymes had tested and verified at least some thermostable variants for the sixteen amino acid positions identified by random mutagenesis, but nothing in the 2000 application demonstrates that it had verified whether any of the remaining seventeen positions predicted by rational protein design (including position 239) actually yielded a thermostable variant. In fact, the 2000 application's limited disclosure compels the opposite conclusion—if Novozymes had possessed a working variant substituted at position 239, it surely would have disclosed that substitution instead of, or at least along with, the nonfunctional S239W substitution in the several pages of the 2000 application devoted to listing exemplary substitutions. *See* '23 patent col. 7 l. 40–col. 16 l. 37.

In this way, the present case is also distinguishable from *Union Oil,* upon ***1350** which Novozymes relies. *Union*

Oil involved claims to gasoline compositions capable of reducing tailpipe emissions, and the claims defined the compositions in terms of various chemical and physical properties. There, the patentee described relationships linking certain chemical and physical properties of gasoline compositions to the compositions' emissions profiles. In doing so, the patentee relied on the knowledge of those skilled in the relevant art to extrapolate the undisclosed, but claimed, compositions from their recited properties. In that case, the record indicated that a recitation of particular physical and chemical properties of a gasoline composition necessarily conveyed simultaneous possession of the actual recipe for making that composition because of the recognized level of standardization and predictability in mixing various petroleum stocks to achieve particular properties in the resulting gasoline products. *See Union Oil,* 208 F.3d at 999.

In contrast, one of ordinary skill in the art reading the 2000 application would have understood that Novozymes had only predicted that at least some mutations at position 239 would yield variants with increased thermostability, not that it possessed or had definitively identified any mutations that would do so. The parties' experts agreed that one could not know which, if any, individual substitutions at any of the seventeen sites selected by rational protein design would yield increased thermostability without actually making and testing the variants. In fact, DuPont's later empirical work showed that only six of the nineteen possible substitutions at position 239 actually conferred increased thermostability. Novozymes nonetheless maintains that one of ordinary skill in the art directed to position 239 would have known how to test every possible variant at that position and thus would have found the claimed variants as a matter of course. That argument misses the point, however. The question before us is not whether one of ordinary skill in the art presented with the 2000 application would have been enabled to take those final steps, but whether the 2000 application "discloses the [variants] to him, specifically, as something appellants actually invented." *Ruschig,* 379 F.2d at 995.

[9] In this case, to actually possess the variant enzymes claimed in the ′ 23 patent would have required Novozymes to confirm its predictions by actually making and testing individual variants or at least identifying subclasses of variants that could be expected to possess the claimed properties, which it did not do before filing the 2000 application. At best, the 2000 application describes a roadmap for producing candidate alpha-amylase variants and then determining which might exhibit enhanced thermostability. A patent, however, "is not a reward for the search, but compensation for its successful conclusion." *Ariad,* 598 F.3d at 1353 (quoting *University of Rochester,* 358 F.3d at 930 n. 10). For that reason, the written description requirement prohibits a patentee from "leaving it to the ... industry to complete an unfinished invention." *Id.*

In our view, this case is very analogous to *University of Rochester,* where the patent specification failed to disclose any compounds that could be used in the claimed methods, which required administering a drug having a certain selective activity (inhibiting PGHS–2 activity in a human host).[7] We stated: "[T]he ′850 patent ***1351** does not disclose just *which* peptides, polynucleotides, and small organic molecules have the desired characteristic of selectively inhibiting PGHS–2. Without such disclosure, the claimed methods cannot be said to have been described." 358 F.3d at 927 (citation and internal quotation marks omitted).

[7] PGHS–2, also known as COX–2, is an enzyme produced by human cells in response to certain inflammatory stimuli. PGHS–2 is believed to play an important role in the inflammation associated with diseases such as arthritis. *University of Rochester,* 358 F.3d at 917.

In sum, we agree with the district court that no reasonable jury could conclude that the 2000 application provides adequate written description to support the later-filed claims of the ′23 patent.

CONCLUSION

We have considered Novozymes's remaining arguments and find them unpersuasive. Accordingly, we conclude that the claims of the ′23 patent are invalid for failure to satisfy the written description requirement of § 112, ¶ 1. We therefore affirm the district court's entry of judgment as a matter of law on that basis.

AFFIRMED.

COSTS

No costs.

RADER, Chief Judge, dissenting.

Although a separate written description requirement, and the vague notion of "possession" that it embodies, still troubles me, *see Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1361 (Fed.Cir.2010) (Rader, J., dissenting-in-part and concurring-in-part), I write today to ask the court instead to give full attention to the rules that it has created. The written description inquiry is a question of fact. *Ariad,* 598 F.3d at 1351. In this case, a jury found—in its role as a finder of fact—that the specification of U.S. Patent No. 7,713,723 (the '23 patent) satisfies the written description requirement. In my judgment, substantial evidence supports the jury's verdict, which deserves significant deference. Therefore, I would respectfully suggest that our written description rules urge reversing the district court's post-verdict grant of judgment.

I.

The written description analysis requires an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad* at 1351. In this field of technology, the level of skill is high. A skilled artisan would possess an advanced degree and have experience in sophisticated protein design and engineering techniques. *See* J.A. 11242–43. The jury found as a matter of fact that a skilled artisan would know to substitute an amino acid as the invention suggests. Indeed, the patent identifies thirty-three positions for beneficial mutation on a Termamyl-like alpha-amylase. In this field, the highly skilled artisan would find that disclosure more than adequate to direct the substitution of an amino acid at one of those positions. The jury made that finding. Substantial evidence supports that finding.

The specification of the '23 patent discusses variants of Termamyl-like alpha-amylases with altered stability at "high temperature and/or low pH conditions, in particular at low calcium concentrations." '23 patent col. 1 ll. 30–33. The specification includes listings for seven different parent alpha-amylases (including both BSG and BLA), and explains that variants can be made "comprising an alteration at one or more positions ... selected from the group of [thirty-three positions]." *Id.* col. 7 ll. 36–43. The specification teaches that any amino acid can be substituted at those positions. *Id.* col. 2 ll. 21–30; *see also* J.A. 10256–57.

The specification also discloses two working examples, which used random mutagenesis to identify sixteen positions at which substitutions led to increased thermostability at pH 4.5, 90 ° C and 5 ppm ***1352** calcium (the claimed conditions). '23 patent col. 25–26. The examples all use BLA as the parent alpha-amylase. Dr. Arnold testified that the specification fully discloses the tests for determining activity and thermostability at the claimed conditions. *See* J.A. 11248 (discussing disclosure in the '23 patent relating to assays). She also noted that these procedures were well-known in this field. *Id.*

The jury heard expert testimony that "finding the position where you can make a beneficial mutation is, in fact, the inventive step," and that once those positions are known, the procedure for making the substitutions was routine and well known, as was the process for determining which substitutions would result in the desired properties. *See* J.A. 11228–48. Novozymes also presented expert testimony to support its assertion that, while the specification explains that each alteration may be a deletion, insertion, or substitution of an amino acid, or a combination of these, a skilled artisan reading the specification would have focused on substitutions. *See* J.A. 11263–70. Making and testing all nineteen amino acid substitutions at one position was routine and would only take one week. J.A. 11251. In other words, a team of ten scientists could test all thirty-three positions with relative ease.

The court states: "the 2000 application disclosed a potentially enormous number of alpha-amylase variants, encompassing all possible combinations among the seven disclosed parent enzymes, the thirty-three disclosed positions for mutations possible at each position, and the various possible combinations of individual mutations...." Majority Op. at 1342–43. This conclusion overstates the problem in a way that appeals to a lay audience but is routine to this field. Novozymes offered expert testimony that this calculation, while mathematically correct, is unrealistic because skilled artisans would not blindly try random combinations. J.A. 10935–36; *see also Snitzer v. Etzel,* 59 C.C.P.A. 1242, 465 F.2d 899, 903 (1972) (concluding appellee's reliance on a theoretical calculation of billions of possible combinations was "hopelessly exaggerated" when the specification directed persons of skill in the art to fourteen ions that could be used "in various combinations"). This court might also

have credited the patentee with reducing the original 500 total amino acid positions down to a mere thirty-three. J.A. 10936.

II.

In conclusion, the jury received expert testimony, heard from skilled protein engineers, reviewed visual aids and publication excerpts, and examined the patent document as guided by those skilled in the art, over an eight day trial. The jury was given a special verdict form asking whether DuPont had proven by clear and convincing evidence that the claims at issue were invalid for lack of written description. J.A. 216. The jury answered in favor of Novozymes, and substantial evidence supports this determination. Therefore, I would reverse the grant of judgment as a matter of law and reinstate the jury's verdict.

All Citations

723 F.3d 1336, 107 U.S.P.Q.2d 1457

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18 F.4th 1333
United States Court of Appeals, Federal Circuit.

BIOGEN INTERNATIONAL GMBH, Biogen MA, INC., Plaintiffs-Appellants
v.
MYLAN PHARMACEUTICALS INC., Defendant-Appellee

2020-1933
|
Decided: November 30, 2021

Synopsis
Background: Owner of patent for method of treating multiple sclerosis brought infringement action against generic drug manufacturer. Manufacturer counterclaimed for declaratory judgment that the patent was invalid and not infringed. Following bench trial, the United States District Court for the Northern District of West Virginia, No. 1:17-cv-00116-IMK-JPM, Irene M. Keeley, J., 2020 WL 3317105, determined that the asserted claims of patent were invalid for lack of written description. Owner appealed.

[Holding:] The Court of Appeals held that district court did not clearly err in determining that asserted claims in patent were invalid for lack of written description.

Affirmed.

O'Malley, Circuit Judge, filed a dissenting opinion.

Procedural Posture(s): On Appeal; Judgment.

West Headnotes (18)

[1] **Patents** Questions of law or fact
Patents Specification and description; enablement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(10)Questions of law or fact
291Patents
291VIIPatent Infringement
291VII(C)Actions
291VII(C)7Appellate Review
291k1965Scope, Standard, and Extent of Review
291k1970Particular Matters
291k1970(9)Patent Applications and Proceedings
291k1970(11)Specification and description; enablement

Whether patent claim meets written-description requirement is question of fact, which Court of Appeals reviews for clear error on appeal from bench trial.

2 Cases that cite this headnote

[2] **Federal Courts** "Clearly erroneous" standard of review in general
Federal Courts Definite and firm conviction of mistake

170BFederal Courts
170BXVIICourts of Appeals
170BXVII(K)Scope and Extent of Review
170BXVII(K)2Standard of Review
170Bk3576Procedural Matters
170Bk3603Findings
170Bk3603(2)"Clearly erroneous" standard of review in general
170BFederal Courts
170BXVIICourts of Appeals
170BXVII(K)Scope and Extent of Review
170BXVII(K)2Standard of Review
170Bk3576Procedural Matters
170Bk3603Findings
170Bk3603(7)Definite and firm conviction of mistake

Clear-error standard of review requires courts to exercise deference when reviewing findings of fact, unless there is definite and firm conviction that mistake has been made.

2 Cases that cite this headnote

[3] **Patents** Weight and sufficiency

291Patents

291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(7)Evidence
291k907(9)Weight and sufficiency

Patent invalidity under written-description doctrine must be established by clear and convincing evidence.

[4] **Federal Courts**Credibility and impeachment

170BFederal Courts
170BXVIICourts of Appeals
170BXVII(K)Scope and Extent of Review
170BXVII(K)2Standard of Review
170Bk3576Procedural Matters
170Bk3599Witnesses
170Bk3599(3)Credibility and impeachment

Courts of appeals cannot reweigh district court's assessment of witness credibility, and must take into account the unchallenged superiority of a district court's ability to make witness-credibility determinations and findings of fact.

[5] **Patents**Written Description Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general

To secure a patent for an invention under the laws of the United States, an inventor must comply with the written-description requirement. 35 U.S.C.A. § 112.

1 Case that cites this headnote

[6] **Patents**Possession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention

Possession of the claimed subject matter, as shown in disclosure in specification of patent, represents the hallmark of written-description requirement to patent specification. 35 U.S.C.A. § 112.

3 Cases that cite this headnote

[7] **Patents**Disclosure as directed to one skilled in the art
PatentsPossession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(2)Disclosure as directed to one skilled in the art
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention

Written-description requirement for patent specification is satisfied only if the inventor conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrates that by disclosure in the specification of the patent. 35 U.S.C.A. § 112.

6 Cases that cite this headnote

[8] **Patents**Possession of claimed invention

291Patents

291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention

A precise definition of the invention is pivotal to establishing possession, as required to satisfy written-description requirement to patent specification. 35 U.S.C.A. § 112.

2 Cases that cite this headnote

[9] **Patents**Possession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention

An applicant for a patent may show possession of the claimed invention by describing it with all of its limitations using such descriptive means as words, structures, figures, diagrams, formulas, etc.

2 Cases that cite this headnote

[10] **Patents**Disclosure as directed to one skilled in the art
PatentsPossession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(2)Disclosure as directed to one skilled in the art
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention

The term "possession" in the context of written-description requirement to patent specification entails an objective inquiry into the four corners of the specification from the perspective of a skilled artisan. 35 U.S.C.A. § 112.

6 Cases that cite this headnote

[11] **Patents**Written Description Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general

Whether claimed invention satisfies written description requirement of patent specification will depend on nature of invention; thus, the written-description analysis is highly dependent on the facts of each case. 35 U.S.C.A. § 112.

4 Cases that cite this headnote

[12] **Patents**Written Description Requirement
PatentsEvidence

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general
291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(7)Evidence
291k907(8)In general

In general, written description in patent specification is judged based on state of art as of priority date; evidence illuminating state of art subsequent to priority date is not relevant to written description. 35 U.S.C.A. § 112.

2 Cases that cite this headnote

[13] **Patents** Particular products or processes

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(6)Particular products or processes

District court did not clearly err in determining that patentee's original disclosure in patent specification did not disclose a method to administer a therapeutically effective dose of drug for the treatment of multiple sclerosis (MS), and thus that asserted claims in patent were invalid for lack of written description; even assuming that a skilled artisan would understand disclosure to be unambiguously focused on MS despite its inclusion among approximately three dozen neurological disorders, the skilled artisan would then look in the specification for guidance vis-à-vis a suitable therapeutic dosage, but dose was listed only once in the entire specification, at the end of one range among a series of ranges, and not listed as an independent therapeutically efficacious dose. 35 U.S.C.A. § 112.

3 Cases that cite this headnote

[14] **Patents** Possession of claimed invention

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(3)Possession of claimed invention

To satisfy the written description requirement to patent specification, an inventor need not prove that claimed pharmaceutical compound actually achieves certain result, but when inventor expressly claims that result, such result must be supported by adequate disclosure in specification. 35 U.S.C.A. § 112.

[15] **Patents** Written Description Requirement

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(1)In general

The written-description requirement of patent specification limits patent protection only to individuals who perform the difficult work of producing a complete and final invention featuring all its claimed limitations and publicly disclose the fruits of that effort. 35 U.S.C.A. § 112.

[16] **Patents** Particular products or processes

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(6)Particular products or processes

District court's factual determination that it was not necessary or appropriate to distinguish between the therapeutic effects and clinical efficacy of patented method for treating multiple sclerosis, when considering the validity of patent under the written-description requirement, was not clearly erroneous; specification's definition of "therapeutically effective dose" indisputably featured both clinic and therapeutic insignia. 35 U.S.C.A. § 112.

[17] **Patents** In general; utility

291Patents
291XPatents Enumerated

291k2091In general; utility

US Patent 8,399,514. Invalid.

[18] **Patents** In general; utility

291Patents
291XPatents Enumerated
291k2091In general; utility

US Patent 6,509,376, US Patent 7,320,999, US Patent 7,619,001, US Patent 7,803,840, US Patent 8,759,393. Cited.

***1335** Appeal from the United States District Court for the Northern District of West Virginia in No. 1:17-cv-00116-IMK-JPM, Judge Irene M. Keeley.

Attorneys and Law Firms

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Before O'malley, Reyna, and Hughes, Circuit Judges.

Opinion

Dissenting opinion filed by Circuit Judge O'Malley.

Reyna, Circuit Judge.

This appeal from the United States District Court for the Northern District of West Virginia concerns a patent-infringement dispute between Biogen International GmbH, Biogen MA, Inc., and Mylan Pharmaceuticals, Inc. Biogen owns United States Patent 8,399,514 (the '514 Patent), which claims a method of treating multiple sclerosis with a drug called dimethyl fumarate. In 2017, Biogen filed a lawsuit against Mylan alleging patent infringement. Mylan counterclaimed for declaratory judgment that the patent was invalid and not infringed. Following a bench trial, the district court determined that the asserted claims of the '514 Patent were invalid for lack of written description. Biogen challenges the district court's decision on appeal.

For the reasons set forth in this opinion, we hold that the district court did not clearly err in determining that Mylan has established its burden of showing, by clear ***1336** and convincing evidence, that the asserted '514 Patent claims are invalid for lack of written description under 35 U.S.C. § 112. Accordingly, we affirm the judgment of the district court.

I. BACKGROUND

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), a manufacturer of a new generic drug that is bioequivalent[1] to a previously approved drug may seek approval from the US Food and Drug Administration (FDA) to market the generic product by filing an Abbreviated New Drug Application (ANDA). *See* Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585–86 (1984) (codified as amended at 21 U.S.C. § 355(j)(2)(A)). The statute requires the generic-drug manufacturer to submit a certification regarding the status of any patent that purportedly protects the brand-name drug, including information as to whether no such patent exists or the patent already expired, and if the patent has not expired the manufacturer must indicate the date on which the patent will expire. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(III).

[1] For purposes of Hatch-Waxman litigation, a generic drug is considered bioequivalent to a brand-name drug if:

> (i) the rate and extent of absorption of the [generic] drug do not show a significant difference from the rate and extent of absorption of the listed [brand-name] drug when administered at the same molar dose of the therapeutic ingredient under similar

> experimental conditions in either a single dose or multiple doses; or
> (ii) the extent of absorption of the [generic] drug does not show a significant difference from the extent of absorption of the listed [brand-name] drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

21 U.S.C. § 355(j)(8)(B)(i)–(ii).

If a patent that covers the brand-name drug has not expired, the generic-drug manufacturer may file what is known as a paragraph IV certification, attesting that the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii)(IV). The manufacturer filing the ANDA and paragraph IV certification must promptly notify the owner of any patent subject to the certification. *Id.* § 355(j)(2)(B)(iii). And the FDA must approve the ANDA, unless the patent owner objects by filing an action for patent infringement against the generic-drug manufacturer within forty-five days of receiving notice of the paragraph IV certification. *Id.* § 355(j)(5)(B)(iii). If the patent owner brings the infringement suit under the Hatch-Waxman Act within the statutory period, the law triggers an automatic, thirty-month stay in the FDA-approval process of the generic drug, pending the outcome of the litigation. *See id.* § 355(j)(5)(B)(iii).

Mylan Pharmaceuticals, Inc. (Mylan) filed an ANDA seeking to manufacture, use, and market a generic dimethyl fumarate (DMF) product for the treatment of multiple sclerosis (MS) before the expiration date of the '514 Patent. J.A. 6001–02. On June 30, 2017, Biogen International GmbH and Biogen MA, Inc. (collectively Biogen) sued Mylan for patent infringement in the Northern District of West Virginia pursuant to the Hatch-Waxman Act. *Id.* In its original complaint, Biogen ***1337** asserted six patents[2] purportedly covering Tecfidera®, Biogen's trademarked DMF-capsule formulation for the treatment of patients suffering from relapsing-remitting forms of MS. *Id.* Only the '514 Patent is at issue in this appeal. *See* J.A. 2–3.

[2] In addition to the '514 Patent, Biogen asserted US Patents 6,509,376; 7,320,999; 7,619,001; 7,803,840; and 8,759,393. J.A. 6002.

A. The '514 Patent

The '514 Patent claims priority to United States Provisional Application 60/888,921 (the '921 Application), which Biogen filed on February 8, 2007. U.S. Patent No. 8,399,514, at [60] (filed Feb. 13, 2012) (issued Mar. 19, 2013). As issued, the patent is entitled "Treatment for Multiple Sclerosis." '514 Patent, at [54].

MS is a disabling autoimmune disease that affects the central nervous system (CNS) and involves an abnormal inflammatory response, which leads to damage and the eventual destruction of the myelin sheath that surrounds neuronal axons—the nerve fibers that transmit electrical signals across CNS nerve cells. *See* '514 Patent col. 1 ll. 15–20. The myelin sheath, which comprises a mixture of proteins and lipids, is a substance that acts as a protective covering to insulate nerve fibers—much like the insulation material that surrounds and protects an electrical wire—and permits nerve cells to adequately conduct the electrical signals. *See* John S. O'Brien, *Stability of the Myelin Membrane*, 147 SCIENCE 1099, 1099 (1965); J.A. 4–5. MS-induced deterioration of the myelin sheath interferes with the proper transmission of such electrical signals across nerve cells and eventually contributes to neurodegeneration, death of neurons, and progressive neurological dysfunction in individuals suffering from the disease. *See* '514 Patent col. 1 ll. 17–20, 29–30; J.A. 4–5.

In its action alleging patent infringement against Mylan, Biogen asserted claims 1–4, 6, 8–13, 15, and 16 of the '514 Patent. J.A. 15–17. Claim 1 is representative and recites:

> A method of treating a subject in need of treatment for multiple sclerosis comprising orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of (a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and (b) one or

> more pharmaceutically acceptable excipients, wherein the therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof is about 480 [milligrams] per day [(mg/day)].

Id. col. 27 ll. 59–67. Relevant to this appeal is Biogen's use of DMF, a fumaric-acid ester compound, at a specific dose of 480 mg/day (DMF480) under the brand name Tecfidera® for the treatment of MS.

The '514 Patent specification largely tracks that of the original '921 Application, which Biogen entitled "Nrf2 Screening Assays and Related Methods and Compositions."[3] J.A. 3289–92. The specification casts a wide net for a myriad of neurological disorders, including neurodegenerative diseases such as amyotrophic lateral sclerosis ***1338** (ALS), Parkinson's disease, Alzheimer's disease, and Huntington's disease; demyelinating neurological diseases, such as various forms of MS and at least twenty-eight other disorders related to demyelination; polyneuritis; and mitochondrial disorders with demyelination. *See* '514 Patent col. 16 ll. 18–63. Although the specification does not focus exclusively on MS, it discusses MS-related background information in two paragraphs that appear in the first column. *See id.* col. 1 ll. 15–52.

[3] On February 7, 2008, Biogen filed International Patent Application PCT/US2008/0016902 (the '902 Application), which maintained the same title, claims, and inventor as the '921 Application but added to its specification. J.A. 10. On August 7, 2009, the international '902 Application entered the national phase and became US Patent Application 12/526,296 (the '296 Application). *Id.*

The specification further describes five methods to explore a potential protective role for the activation of the Nrf2 pathway in neurodegenerative and neuroinflammatory diseases. J.A. 66–67. Methods 1–3 relate to screening, evaluating, and comparing the bioequivalence of compounds for their use against neurological diseases. J.A. 68–69. Methods 4 and 5 relate to the *treatment* of such neurological diseases. J.A. 69. Consistent with the disclosure's original title concerning Nrf2 screening, the totality of the specification focuses primarily on drug discovery. Indeed, the invention's title was only amended to "Treatment for Multiple Sclerosis" in 2011 after Biogen acquired Phase III clinical data for the use of DMF480 in treating MS. *See* J.A. 12–13; J.A. 3490–91.

Because the claims at issue concern methods to treat MS, we must look to methods 4 and 5 as disclosed in the specification. Method 5 is largely irrelevant for our purposes because it relates to combination therapy comprising the administration of a compound that upregulates the Nrf2 pathway with at least one other compound that cannot upregulate the pathway. '514 Patent col. 8 ll. 54–63. But method 4 is instructive, as it discloses "methods of treating a neurological disease by administering to the subject in need thereof at least one compound that is at least partially structurally similar to DMF and/or [monomethyl fumarate (MMF)]," as well as "a method of treating a mammal who has or is at risk for a neurological disease ... [by] administering to the mammal a therapeutically effective amount of at least one neuroprotective compound" such as DMF or MMF, and "a method of slowing or preventing neurodegeneration" induced by demyelination or the death or neurons. *Id.* col. 8 ll. 35–53.

Save for one paragraph in the specification, the disclosure does not teach potential dosage levels for DMF monotherapy. The sole DMF-dosage paragraph is not linked to treatment of any specific disease but recites:

> Effective doses will also vary, as recognized by those skilled in the art, dependent on route of administration, excipient usage, and the possibility of co-usage with other therapeutic treatments including use of other therapeutic agents. For example, an effective dose of DMF or MM[F] to be administered to a subject orally can be from about 0.1 g to 1 g per pay, 200 mg to about 800 mg per day (e.g., from about 240 mg to about 720 mg per day; or ***from about 480 mg to about 720 mg per day***; or about 720 mg per day). For example, the 720 mg per day may be administered in separate administrations of 2, 3, 4, or 6 equal doses.

Id. col. 18 ll. 54–64 (emphasis added). As shown above,

the specification explicitly mentions "effective doses" at various concentration ranges within an overall DMF dosage range of 100–1,000 mg/day.

Importantly for this appeal, the specification reveals two crucial aspects of the invention. First, the above paragraph features ***1339** the *one and only* reference to DMF480 in the entire specification, which puts the DMF480 dose that the '514 Patent claims at the bottom end of the spectrum of a DMF 480–720 mg/day range. Second, the specification defines the term "effective" within a therapeutic, rather than drug-discovery, context. Thus, according to the specification, the terms " 'therapeutically effective dose' and 'therapeutically effective amount' refer to that amount of a compound which results in at least one of *prevention* or *delay* of onset or *amelioration of symptoms* of a neurological disorder in a subject or an attainment of a *desired biological outcome, such as reduced neurodegeneration* (e.g., demyelination, axonal loss, and neuronal death) or *reduced inflammation* of the cells of the CNS." *Id.* col. 5 ll. 52–59 (emphases added).

B. Clinical Development and Procedural History

Between 2004 and 2006, Biogen conducted a Phase II, clinical, dose-ranging study to test the efficacy of DMF at 120, 360, and 720 mg/day concentrations (DMF120, DMF360, and DMF720, respectively) for the treatment of MS. J.A. 2184–91. The May 2006 results of this study showed that DMF720 was efficacious in treating MS, but DMF120 and DMF360 were not. J.A. 7. In August 2006, the FDA recommended that Biogen add a DMF480 dosing regimen in the Phase III study because the lower dose "might improve patient compliance and/or minimize dropouts from adverse effects during the study." J.A. 1724–25. According to Biogen, the Phase II lead scientist, Dr. O'Neill, had conceived the idea of using DMF480 as early as 2003 and advocated testing the DMF480 dose as part of the trial in February 2004. J.A. 7. At the time, Biogen had decided not to include the DMF480 dose in the study for commercial reasons. *See* J.A. 1364. Although Biogen told the FDA that DMF720 was the best option, it eventually included DMF480 in the Phase III clinical testing. *See* J.A. 1726. The Phase III results showed efficacy for the DMF480 and DMF720 doses. J.A. 2060.

Based on the 2006 Phase II results—and before starting the Phase III trial to test the DMF480 dose—Biogen filed the provisional '921 Application on February 8, 2007. The original application listed Dr. Lukashev, a Biogen scientist who, at the time, focused on research related to the Nrf2 pathway, as the sole inventor. J.A. 8–10. O'Neill was not listed as a co-inventor on the '921 Application; his name was added in 2011 as part of an amendment refocusing the invention on methods of treatment for MS, which Biogen filed after gathering the Phase III results that demonstrated therapeutic efficacy of DMF480.[4] J.A. 3437–39; J.A. 3481–86. O'Neill, however, had not been involved with any of the Nrf2 research that led to the '514 Patent. When asked during trial, Lukashev testified that he did not know why O'Neill was added as an inventor. J.A. 1318. Lukashev ***1340** also corroborated the original application's emphasis on drug discovery by noting that his work had encompassed "a more exploratory nature. It[was] to explore potential for follow-on compound discovery ...." J.A. 9 (alteration in original). And, more importantly, he "denied that his research could be extrapolated to a clinical dose of DMF; it 'was never the focus of [his] work to inform the clinical dosing of [DMF].' " *Id.* (alterations in original). Besides the amendments related to inventorship and the invention's title, Biogen did not make any other changes to the specification. This enabled Biogen to claim a priority date of February 8, 2007, despite filing wholly new claims alongside the amendments. J.A. 13.

[4] Biogen amended the '296 Application—the national-phase application filed in 2009, *see supra* note 3—after acquiring its Phase III clinical-data results in April 2011. J.A. 10. Biogen left the specification of the '296 Application unchanged, but it amended the invention's title and claims on June 20, 2011. J.A. 47. On October 28, 2011, Biogen subsequently amended the '296 Application again to add O'Neill as an inventor. *Id.* Biogen then abandoned the '296 Application in favor of US Patent Application 13/326,426 (the '426 Application), a continuing application filed on February 13, 2012. J.A. 11. The '426 Application eventually led to issuance of the '514 Patent on March 19, 2013. *Id.* Biogen claims a February 8, 2007 priority date for the '514 Patent based on the '921 Application. *Id.*

In 2017, Biogen filed its patent infringement suit against Mylan in the Northern District of West Virginia. J.A. 6001. Biogen sued after Mylan sought ANDA approval to market a generic DMF product for treating MS. Mylan counterclaimed for declaratory judgment that the '514 Patent was invalid and not infringed. J.A. 6136–44. The district court held a four-day bench trial starting on February 4, 2020. J.A. 1001. On February 5, 2020, the Patent Trademark and Appeal Board (Board) issued a final written decision in a related inter partes review (IPR) proceeding, which Mylan initiated on July 13, 2018 and is

the subject of a companion case to this appeal. *See Mylan Pharms. Inc. v. Biogen MA Inc.*, No. IPR2018-01403, 2020 WL 582736 (P.T.A.B. Feb. 5, 2020). In the IPR case, the Board rejected an obviousness challenge to the asserted '514 Patent claims, which estopped Mylan from litigating obviousness issues in the trial court. *See* J.A. 3 n.2.

During trial, the parties agreed that, for purposes of this case, a person of ordinary skill in the art (POSA) is someone with "at least a medical degree, at least three years of training in neurology, and at least three years of clinical experience treating multiple sclerosis patients." J.A. 20. The parties presented expert testimony from two neurologists who treat patients with MS—Dr. Greenberg for Mylan and Dr. Wynn for Biogen. J.A. 20. At the conclusion of the trial, the district court found that the specification did not reasonably convey to a POSA that the '514 Patent inventors had "actually invented" a method of treating MS with a therapeutically effective dose of DMF480 as of February 8, 2007. J.A. 45. The court also found that Biogen's arguments and Wynn's testimony that a POSA would be drawn to the DMF480 dose upon reading the patent specification were "neither credible nor persuasive," J.A. 30–31, and noted that Wynn conceded during cross examination that the sole DMF-dosage paragraph in the specification did not teach a POSA that DMF480 would be therapeutically effective for treating MS, J.A. 31.

The district court opined that Biogen's attempt to "combin[e] a few selectively[ ]plucked disclosures from the specification ... has been squarely rejected by the Federal Circuit." J.A. 45. Based on the testimony offered at trial, the context of the '514 Patent prosecution history, and "significant omissions from the specification," the district court ultimately concluded that Mylan had satisfied its burden of showing by clear and convincing evidence that the asserted '514 Patent claims were invalid for lack of written description under 35 U.S.C. § 112. *Id.* Biogen now appeals the district court's decision.

II. STANDARD OF REVIEW

[1] [2] [3] [4]Whether a claim meets the written-description requirement is a question ***1341** of fact, which this court reviews for clear error on appeal from a bench trial. *Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Laboratories Inc.*, 923 F.3d 1368, 1376 (Fed. Cir. 2019), *cert. denied*, —— U.S. ——, 140 S. Ct. 902, 205 L.Ed.2d 464 (2020). The clear-error standard requires courts to exercise deference when reviewing findings of fact, unless there is a "definite and firm conviction that a mistake has been made." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1374 (Fed. Cir. 2008) (internal quotation marks and citation omitted). Patent invalidity under the written-description doctrine must be established by clear and convincing evidence. *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011). Courts of appeals cannot reweigh a district court's assessment of witness credibility, *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 832 (Fed. Cir. 2010), and must take into account the "unchallenged superiority" of a district court's ability to make witness-credibility determinations and findings of fact, *see Salve Regina Coll. v. Russell*, 499 U.S. 225, 233, 111 S.Ct. 1217, 113 L.Ed.2d 190 (1991).

III. DISCUSSION

A. The Written-Description Requirement

[5] [6]To secure a patent for an invention under the laws of the United States, an inventor must comply with the written-description requirement outlined in 35 U.S.C. § 112, which prescribes:

> The [patent] specification shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.[5]

35 U.S.C. § 112 (emphasis added). The statutory mandate for a written description as a prerequisite for patenting an invention has been a fixture of our laws for more than two centuries. The Supreme Court recognized, as far back as 1822, that the purpose of requiring a written description under the Patent Act of 1793 was to "put the public in possession of what the party claims as his own invention, so as to ascertain if he claim[s] anything that is in common use, or is already known ...." *Evans v. Eaton*, 20 U.S. 356, 434, 7 Wheat. 356, 5 L.Ed. 472 (1822). "[P]ossession as shown in the disclosure," therefore, represents the hallmark of written description. *Ariad*

Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The written-description statutory language has undergone little change despite the enactment and revisions of numerous patent statutes since the Founding era. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 925 (Fed. Cir. 2004).

[5] Following the enactment of the Leahy–Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat 284 (2011), the first paragraph of § 112 was redesignated as § 122(a). The AIA amendments, which took effect on September 16, 2012, replaced the words "of carrying out his invention" in the pre-AIA § 112 with "or joint inventor of carrying out the invention" in the current § 122(a). 125 Stat. at 296–97. The amendments bear no significance for purposes of our written-description analysis.

[7] [8] [9] [10]This court's precedents dictate that the § 112 written-description "requirement is satisfied only if the inventor 'convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the ***1342** invention,' and demonstrate[s] that by disclosure in the specification of the patent." *Nuvo*, 923 F.3d at 1376–77 (quoting *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, 636 F.3d 1341, 1348 (Fed. Cir. 2011)). A precise definition of the invention is pivotal to establishing possession. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1373 (Fed. Cir. 2017). An applicant may show possession of the claimed invention by describing it with all of its limitations using "such descriptive means as words, structures, figures, diagrams, formulas, etc." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). The term "possession" in the context of written-description jurisprudence entails an "objective inquiry into the four corners of the specification from the perspective of a [skilled artisan]." *Ariad*, 598 F.3d at 1351.

[11] [12]Whether a claimed invention satisfies the written-description requirement of § 112 will depend on the nature of the invention. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 963 (Fed. Cir. 2002) (citations omitted). Thus, the written-description analysis is highly dependent on the facts of each case. *Nuvo*, 923 F.3d at 1383 (citations omitted). In general, "written description is judged based on the state of the art as of the priority date.... [E]vidence illuminating the state of the art subsequent to the priority date is not relevant to written description." *Amgen*, 872 F.3d at 1373–74 (internal citation omitted).

B. Possession of the Claimed Invention

[13]The core issue in this appeal is whether the specification Biogen filed on February 8, 2007 supports the 2011 claims that issued in the '514 Patent. Even more precisely, the narrow ground on which this question turns is whether the original specification describes "possession" of the claimed therapeutically effective DMF480-dose limitation to treat MS.

The district court began by properly noting that "it is the specification itself that must demonstrate possession." J.A. 23 (quoting *Ariad*, 598 F.3d at 1352). The specification covers a broad array of nearly three dozen neurological disorders, and MS may arguably constitute an important element of the disclosure from the start. *See* '514 Patent col. 1 ll. 12–52 (explaining that the overall purpose of the invention is to treat "demyelinating neurological diseases," such as MS). Next, DMF appears more than two-dozen times throughout the specification, including in the three examples listed in the disclosure. The prior art demonstrates the existence of a link between DMF-mediated activation of the Nrf2 pathway and the neuroprotective and therapeutic effects of said activation, which could be exploited for the treatment of certain neurological disorders such as MS. *See id.* col. 5 ll. 20–24. Thus, assuming that a skilled artisan would understand the disclosure to be unambiguously focused on MS despite its inclusion among approximately three-dozen neurological disorders—a determination we need not reach in this case—the specification may arguably provide adequate information to convey to a skilled artisan that the invention supports method-of-treatment claims directed to MS and, perhaps, that the use of DMF may be therapeutically linked to MS treatment.[6]

[6] We note, however, that method 4, which is the only relevant method to this appeal, is devoid of any specific reference to MS. *See* '514 Patent col. 8 ll. 35–53; J.A. 27 (noting that MS is merely listed as one of a slew of neurological diseases). The district court further found that Mylan's expert "credibly testified" that nothing in the specification "ties an effective dose of DMF specifically to the treatment of MS." J.A. 29.

***1343** The skilled artisan would then look in the specification for guidance vis-à-vis a suitable therapeutic-DMF dosage. This is where the district court noted the lack of written description, upon which it primarily based its finding of invalidity. The DMF480 dose is listed only once in the entire specification. *See* '514 Patent col. 18 l. 62. The specification's sole

reference to DMF480 constitutes a significant fact that cuts against Biogen's case, particularly because it appears at the end of one range among a series of ranges, including DMF concentrations of 100–1,000, 200–800, 240–720, and 480–720 mg/day. That is in stark contrast to DMF720, which is referenced independently as one dose and was known to be effective as of the February 2007 priority date. The '514 Patent, as issued, features multiple claims that are drawn exclusively to the specific DMF480 dose, but the specification's focus on basic research and broad DMF-dosage ranges show that the inventors did not possess a therapeutically effective DMF480 dose at the time of filing in 2007. On this point, Lukashev, the original inventor listed in the '921 Application, offered testimony in which he "denied that his research could be extrapolated to a clinical dose of DMF; it 'was never the focus of [his] work to inform the clinical dosing of [DMF].' " J.A. 9 (alterations in original); *see also* J.A. 34 (noting that the district court found Lukashev's testimony credible as to the fact that all the examples listed in the specification were part of his research and would not have been "helpful in identifying a therapeutically effective" DMF dose). Likewise, the district court credited Mylan's expert testimony at trial that the paragraph containing the sole DMF480 reference fails to specifically link an effective dose of DMF to the treatment of MS. J.A. 29.

[14]This court has previously held that "[s]atisfaction of the description requirement [e]nsures that ... a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991) (quoting *In re Smith & Hubin*, 481 F.2d 910, 914 (CCPA 1973)). An inventor need not "prove that a claimed pharmaceutical compound actually achieves a certain result. But when the inventor expressly claims that result, our case law provides that [such] result must be supported by adequate disclosure in the specification." *Nuvo*, 923 F.3d at 1384. Based on the evidence in the record, the district court did not clearly err in determining that Mylan established its burden of showing, by clear and convincing evidence, that the specification does not adequately support the asserted claims of the '514 Patent. More specifically, the district court did not clearly err in finding that a skilled artisan would not have recognized, based on the single passing reference to a DMF480 dose in the disclosure, that DMF480 would have been efficacious in the treatment of MS, particularly because the specification's only reference to DMF480 was part of a wide DMF-dosage range and not listed as an independent therapeutically efficacious dose.

[15]That Biogen later established the therapeutic efficacy of DMF480 is of no import to the written-description analysis. What matters for purposes of the inquiry ***1344** in this case is whether, at the time of filing the disclosure—well before the Phase III study even commenced—a skilled artisan could deduce simply from reading the specification that DMF480 would be a therapeutically effective treatment for MS. As to this point, the specification's focus on drug discovery and basic research further buttresses the district court's conclusion that the specification lacks an adequate written description to support the DMF480 claims. At the time of filing the original disclosure in 2007, the Nrf2 insights that proved critical in the Phase III study had not yet been translated to clinical use. *See* J.A. 35 (finding that, based on the evidence presented at trial, Lukashev's research related to Nrf2 activation and small-molecule screening "had nothing to do with the clinical development of Tecfidera®"). Regardless of whether O'Neill had in fact hypothesized or even conceived the idea of treating MS with a DMF480 dose as early as 2003, *see* J.A. 1586–87, the law is clear that a patent cannot be awarded for mere theoretical research without more, *see Ariad*, 598 F.3d at 1353. The written-description requirement limits patent protection only to individuals who perform the difficult work of producing a complete and final invention featuring all its claimed limitations and publicly disclose the fruits of that effort. *Id.* We therefore determine that, based on the evidence in the record, the district did not clearly err in finding that Biogen did not possess an invention directed to the specific use of a therapeutically effective DMF480 dose for the treatment of MS as of 2007.

Confronted with the lack of a specific reference to DMF480, Biogen and its expert argued that a skilled artisan would be drawn to the DMF480 dose because it was "anchored" to the effective DMF720 dose. J.A. 1548–49. But the very same sentence in the specification that discloses the DMF 480–720 mg/day range also "anchors" DMF240 (a known ineffective dose) to DMF720 (according to the DMF 240–720 mg/day range). *See* '514 Patent col. 18 ll. 54–64. Not only does the specification anchor an ineffective dose, it also expands the purported range of therapeutic efficacy from DMF100 and DMF200 (doses that a skilled artisan would expect to be ineffective) to DMF1,000 (a dose well above the therapeutically effective DMF720 mg/day dose). *See id.* col. 18 ll. 54–64; Appellee's Br. 26. That column 18 of the '514 Patent specification recites several DMF doses in the 100–1,000 mg/day range as "effective" without even identifying a target disease is further indicative that the inventors were not in possession of a complete and final invention as of February 2007.

Lastly, the court noted that Mylan had impeached Wynn's credibility by pointing out his inconsistent statements and evasiveness when asked, during the district court proceedings, why a skilled artisan would be drawn to the purported DMF480 efficacy upon reading the patent specification—all while consistently maintaining that a skilled artisan would not have reasonably expected DMF480 to provide the therapeutic efficacy claimed in the patent during the IPR proceeding. J.A. 31–33. After hearing live testimony from the parties' experts at trial, the district court found that the Biogen expert's opinion that a skilled artisan would be drawn to a DMF480 dose was "neither credible nor persuasive." J.A. 30–31. We discern no principled reason to disturb the district court's assessment as to the credibility of Biogen's expert testimony. *See Salve Regina Coll. v. Russell*, 499 U.S. 225, 233, 111 S.Ct. 1217, 113 L.Ed.2d 190 (1991) (describing the "unchallenged superiority" of ***1345** a district court as to the assessment of witness credibility and making findings of fact); *Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*, 701 F.3d 1351, 1366 (Fed. Cir. 2012) (Reyna, J., dissenting from the denial of the petition for rehearing en banc) (noting that intervention as to issues of fact finding should be limited to instances of clear error, especially given that "an appellate court cannot adequately, if at all, assess credibility of [expert] testimony because the witness is not before [the appellate panel] in person.").

Viewing the record before us in its totality, we discern no clear error in the district court's judgment that Mylan established its burden of showing, by clear and convincing evidence, that the asserted '514 Patent claims are invalid for lack of written description under 35 U.S.C. § 112.

* * *

Biogen raises several ancillary issues in an effort to reverse the district court decision. For example, Biogen claims that the district court "misinterpret[ed] this [c]ourt's 'blaze[-]marks' jurisprudence; fail[ed] to consider the specification as a whole; erroneously appl[ied] judicial estoppel; disregard[ed] the specification's express disclosure of the claimed dose because it was not described as the most preferred; and confus[ed] the written-description requirement with principles of obviousness and unexpected results." Appellant's Br. 2. But our conclusion that the district court did not clearly err in finding the '514 Patent invalid for lack of written description under § 112 renders all these arguments superfluous.

[16]Notably, the Dissent claims that the district court legally erred by conflating therapeutic and clinical efficacy. *See* Dissent Op. at 1348–49, 1350. However, when viewed through the lens of the '514 Patent, this is not a legal issue, but a factual one. The district court, as the finder of fact, did not find it necessary or appropriate to distinguish between therapeutic effects and clinical efficacy based on the specification's definition of "therapeutically effective dose" and the record before it, and such a determination was not clearly erroneous.

Most notably, the specification's definition of "therapeutically effective dose" indisputably features both clinical and therapeutic insignia. For example, the specification defines a "therapeutically effective dose" as an "*amount* of a compound" that results in the "prevention or delay of onset or amelioration of *symptoms of a neurological disorder in a subject*," namely, clinical insignia, "or an attainment of a *desired biological outcome*, such as reduced neurodegeneration (e.g., demyelination, axonal loss, and neuronal death) or reduced inflammation of the cells of the CNS," which constitute therapeutic insignia. '514 Patent col. 5 ll. 52–59 (emphases added).

On redirect examination, Biogen's expert attempted to characterize the specification's definition as solely describing therapeutic effects—"demyelination, axonal loss, and neuronal death" as well as "fewer [brain] scars"—that once could "see on [an] MRI scan, for example." J.A. 1553–54. He distinguished these from clinical endpoints, such as "a person hav[ing] less episodes" or "no[ ] progression" of *symptoms*, including "weakness, numbness, loss of bladder or bowel control, [sight deterioration], [and] less relapses." J.A. 1553. But Biogen's expert did not explain why these improved clinical outcomes would not qualify under the first half of the specification's definition, which focuses on preventing, ***1346** delaying the onset of, or ameliorating "*symptoms of a neurological disorder*" in patients. '514 Patent col. 5 ll. 52–55 (emphasis added).

Based on the record, including at least the specification's definition of a "therapeutically effective dose" and the witness and expert testimony, the district court did not find it necessary to distinguish between therapeutic effects and clinical efficacy with respect to its patentability determination, instead electing to consider both under the specification's definition of "therapeutically effective dose." We determine that such a finding was not clearly erroneous.

Accordingly, we conclude that the district court did not clearly err in determining that the original 2007

disclosure, which focused exclusively on screening compounds for activation of the Nrf2 biological pathway, did not disclose a method to administer a therapeutically effective dose of DMF480 for the treatment of MS. Nor did the district court clearly err in finding that "O'Neill's hypothesis, that a [DMF480 dose] would be efficacious in treating MS, evolved from his review" of confidential information, which a skilled artisan would not have been privy to in 2007 and was never included in the original disclosure. *See* J.A. 35, 42, 1586–87.

Because we hold that the '514 Patent is invalid under the written-description doctrine, we need not reach the merits of the parties' arguments in the companion IPR case.

IV. CONCLUSION

For the reasons set forth in this opinion, we affirm the district court's decision that Mylan satisfied its burden of showing, by clear and convincing evidence, that the asserted '514 Patent claims are invalid for lack of written description under 35 U.S.C. § 112. Viewed in its totality, the record shows that the inventors were not in possession of a method of administering a therapeutically effective dose of DMF480 to treat MS on or before the February 8, 2007 priority date. We have considered the parties' remaining arguments and find them unavailing or do not reach them.

AFFIRMED

O'Malley, Circuit Judge, dissenting.

While I am loath to reverse district court determinations that rely heavily on credibility findings, I must respectfully dissent. There is no dispute over whether the district court erred in finding that Biogen was judicially estopped from drawing a distinction between clinical and therapeutic effects: it did. Mylan calls the error harmless and the majority finds it "ancillary" to its analysis. I, on the other hand, believe this threshold error impacted the district court's entire written description analysis. I would therefore reverse and remand for reconsideration in light of a proper understanding of the distinction between the two effects and the written descriptions needed for each.

I.

A. The district court erred in applying judicial estoppel

As it had tried to do throughout the trial, Biogen explained the distinction between *clinical efficacy* and *therapeutic effects* in its post-trial briefs before the district court. Clinical efficacy involves the type of scientific rigor associated with Phase III clinical trials: the investigative DMF480 dose must produce superior clinical ***1347** endpoints to the standard of care for MS, Rebif®. *See* J.A. 8066. Therapeutic effects, by contrast, "do not require efficacy on clinical endpoints or superior efficacy to existing drugs." *Id.* It, instead, "refer[s] to the amount of [DMF480] which results in ... prevention or delay of onset or amelioration of symptoms of a neurological disorder" like MS. '514 patent, col. 5, ll. 52–55.

Based on this distinction, Biogen took issue in its post-trial brief with Mylan's contention that the '514 patent lacked written description support because "a person of ordinary skill in the art would not have a reasonable expectation that the 480 mg/day [DMF] dose would provide statistically significant and clinically meaningful effectiveness for treating MS." J.A. 8064 (citing Mylan's post-trial brief, which quoted Dr. Dawson's testimony). Biogen pointed out that, in addition to mixing up written description and obviousness inquiries (which I will discuss *infra*), Mylan's argument erroneously assumed that the claims required *clinical* efficacy when they only covered *therapeutic* effects. J.A. 8063–66.

In a two-sentence footnote, the district court concluded that Biogen was judicially estopped from pointing out the distinction between clinical and therapeutic efficacy. *Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 2020 WL 3317105, at *8 n.15 (N.D.W. Va. June 18, 2020). Citing *New Hampshire v. Maine*, 532 U.S. 742, 121 S.Ct. 1808, 149 L.Ed.2d 968 (2001), the district court reasoned that Biogen could not "deliberately chang[e] positions according to the exigencies of the moment." *Id.*

I need not detail why the court's footnote ruling on judicial estoppel constituted an abuse of discretion under Fourth Circuit law. *See Martineau v. Wier*, 934 F.3d 385, 393 (4th Cir. 2019) (setting out a multi-factor test for the judicial estoppel inquiry, which the district court wholly

failed to apply in this case). Biogen's briefs explain this error in detail and neither Mylan nor the majority defends the district court's ruling under that governing law.

I will, however, provide detail on how the erroneous judicial estoppel ruling led the district court to legally err in its interpretation of Federal Circuit written description precedent. In my view, the district court's refusal to acknowledge the difference between *therapeutic* and *clinical* effects evinces a fundamental misunderstanding of what is claimed—and, thus, what requires written description support—in the '514 patent.

The '514 patent explains that neurodegenerative disorders like MS are "characterized by inflammation in parts of the [central nervous system (CNS)], leading to the loss of the myelin sheathing around neuronal axons (demyelination), loss of axons, and the eventual death of neurons, oligodendrocytes and glial cells." '514 patent, col. 1, ll. 17–20. The '514 patent discusses the promise of treating MS using DMF, "a member of a large group of anti-oxidant molecules known for their cytoprotective and anti-inflammatory properties." '514 patent, col. 5, ll. 16–18. The '514 patent claims a "therapeutically effective amount" of DMF480, which the specification defines as

> that amount of a compound which results in at least one of prevention or delay of onset or amelioration of symptoms of a neurological disorder in a subject or an attainment of a desired biological out-come, such as reduced neurodegeneration (e.g., demyelination, axonal loss, and neuronal death) or reduced inflammation of the cells of the CNS.

'514 patent, col. 5, ll. 52–59.

Notably, the '514 patent explains that the inventors measured DMF's *therapeutic* ***1348** efficacy in terms of its ability to enhance the expression levels of Nrf2—a transcription factor that activates the expression of genes responsible for protecting cells from the neurodegeneration commonly associated with MS. *See* '514 patent, col. 5, ll. 16–24; *see also* '514 patent, col. 1, ll. 35–62. Figures 3 and 4 of the '514 patent provide *in vivo* data showing an increase in Nrf2 expression following DMF treatment. '514 patent, Figures 3 and 4; *see also* '514 patent, col. 22, ll. 1–13. And, the '514 patent states: "the finding that *DMF activates the Nrf2 pathway* ... offers a rationale for identification of structurally and/or mechanistically related molecules that would be expected to be *therapeutically effective* for the treatment of neurological disorders, such as, e.g., MS." '514 patent, col. 5, ll. 19–24 (emphasis added). Taken together, it is clear on the face of the '514 patent that the claimed "*therapeutically* effective amount" refers to DMF's ability to mitigate MS symptoms vis-à-vis its modulation of Nrf2 expression; it has nothing to do with whether DMF480 outperforms the standard of care for MS (Rebif®) in a Phase III clinical trial setting.

It is no wonder, then, why Biogen—in response to Mylan's repeated contentions that the '514 patent fails the written description requirement because it lacks Phase III *clinical* efficacy data—sought in its post-trial briefing to remind the district court that the written description inquiry should focus on *therapeutic* efficacy.[1] Far from deliberately changing positions as the district court accused it of, Biogen was simply attempting to direct the district court's attention to the claim language at issue. Judicially estopping Biogen from doing so was not just legally erroneous under Fourth Circuit law, it misapplied our written description precedents by ignoring the claims at a time when they should have been given primacy. *Cf. Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) ("It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.") (citations omitted) (internal quotation marks omitted).[2]

[1] To be sure, Mylan continues its erroneous conflation of therapeutic and clinical efficacy before our court. *See, e.g.*, Appellee's Resp. Br. at 48–49.

[2] The majority's argument that there is no ascertainable difference between clinical and therapeutic efficacy is wrong for several reasons. *See* Maj. Op. at 1345–46. As I have detailed above, the '514 patent makes clear that "therapeutically effective amount" does not involve comparing the claimed DMF480 dosage to the standard of care for MS like a clinical trial would. And, neither party ever argued this—either to the district court or on appeal. Biogen, instead, advocated distinguishing the two while Mylan and the district court blithely proceeded as though there were no difference without ever providing any explanation. To make up for this deficiency in the trial record, the

> majority provides its own explanation: "clinical insignia" is somehow encompassed by the '514 patent's definition of "therapeutically effective dose." *Id.* (citing '514 patent, col. 5, ll. 52–59). The majority appears to forget our role in this appeal: we are a court of review, not the primary factfinder. To the extent the majority fashions its own explanation of why therapeutic and clinical efficacy are one in the same, it crosses that line.

As discussed further below, the impact of the district court's errant refusal to acknowledge the difference between *therapeutic* and *clinical* efficacy is evident throughout the rest of the opinion.

B. The district court's conflation of therapeutic and clinical efficacy caused it to erroneously require clinical data, rather than therapeutic effects

The district court's failure to distinguish therapeutic effects and clinical efficacy also ***1349** led it to conflate concepts of obviousness and written description. This conflation, in my view, caused the district court to erroneously require a showing of clinical data akin to what would be gathered in Phase III clinical trials in its written description analysis.

Somewhat circularly, after acknowledging that clinical data demonstrating effectiveness is not required to satisfy written description, the district court went on to find that the '514 patent does not demonstrate possession because it lacks clinical efficacy data. *Biogen*, 2020 WL 3317105, at *15. To arrive at this conclusion, the district court relied on its interpretation of our precedent in *Nuvo.* According to the district court, the patentees in *Nuvo* could not establish possession because a POSA "would not have expected [the claimed drug] to be effective, and nothing in the specification would teach a [POSA] otherwise." *Id.* (quoting *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1377, 1381 (Fed. Cir. 2019) (alteration in original). The district court reasoned that the same set of facts are at issue in this case: because Biogen had defended against Mylan's obviousness challenges in this case and a related *inter partes* review proceeding by contending that a POSA would not have expected the DMF480 dose to *clinically* treat MS, the '514 patent's failure to teach a POSA otherwise with clinical data dooms Biogen's written description arguments. *Id.* (citing *Nuvo*, 923 F.3d at 1381).

This cannot be right. Whether a claim satisfies the written description requirement of § 112 is a question of fact that we review for clear error. *Ariad Pharms. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). We provide de novo review, however, of a district court's interpretation of Federal Circuit precedent. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1337 (Fed. Cir. 2003). Our court has long held that "the hallmark of written description is disclosure," meaning that a patent must "reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351.

Here, the district court's reading of *Nuvo* does not accurately describe what we actually held in that case. The patent at issue in *Nuvo* claimed an acid inhibitor that was *uncoated* and *effective* at raising pH levels. *Nuvo*, 923 F.3d at 1373–1374, 1378. The patent specification in *Nuvo*, however, specifically discussed a known problem in the prior art involving *uncoated* acid inhibitors' *ineffectiveness* at raising pH levels. *See id.* at 1375 (reversing the district court for "not explain[ing] why the mere disclosure of [uncoated acid inhibitors], coupled with the known disadvantages of coated [acid inhibitors], is relevant to the therapeutic effectiveness of uncoated [acid inhibitors], *which the patent recognized as problematic for efficacy due to its potential for destruction by stomach acid*") (emphasis added). Since the patentees in *Nuvo* did nothing to explain how the invention purported to overcome the commonly known problem with *uncoated* formulations that the patent specification explicitly discussed, our court invalidated the patent for lack of written description. *Id.* at 1381. Nowhere in *Nuvo* did we overlay a POSA's reasonable expectation of success from the obviousness context onto the written description inquiry. To the extent *Nuvo* mentioned a POSA's expectations, it cabined this discussion to what a POSA would have expected based on the explicit teachings of the patent specification—not of the prior art. *See* ***1350** *id.* at 1381 ("In light of the fact that the specification provides nothing more than the mere claim that uncoated [acid inhibitors] might work, even though persons of ordinary skill in the art would not have thought it would work, the specification is fatally flawed.").

The district court's reliance on *Nuvo* to conclude that Mylan could use Biogen's own obviousness defenses against it in the written description context is, therefore, legally erroneous. What a POSA would expect regarding

clinical efficacy based on the prior art is a distinct question from whether a POSA would understand that the inventor possessed the *claimed* invention—i.e., a therapeutically effective dose—based on the patent's written description. Since the district court never engaged in a proper written description inquiry, I would reverse and remand for further proceedings consistent with a proper written description analysis that minds the gaps between obviousness and written description, as well as therapeutic and clinical efficacy.[3]

[3] To the extent the majority accuses the dissent of reweighing the district court's credibility determinations, I disagree. *See* Maj. Op. at 1344–45. Because I believe the district court's misguided interpretation of *Nuvo* led it to erroneously require clinical efficacy data for the written description inquiry, any expert witness testimony on which the district court relied to bolster that requirement is also legally unsound.

C. The district court's conflation of therapeutic and clinical efficacy caused it to erroneously apply our "blaze marks" precedent

The majority relieves me of the need to discuss the district court's erroneous conclusion that the '514 patent does not contain enough "blaze marks" to direct a POSA toward MS treatment. *See Biogen*, 2020 WL 3317105, at *10 ("Method 4 broadly describes treating neurological diseases with a therapeutically effective amount of DMF; MS is merely one such disease 'among a slew of competing possibilities.' ") (citing *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013)). The majority opinion—appearing to recognize this obvious error—says it operates under the assumption that the '514 patent satisfies written description in this regard. Maj. Op. at 1342–43. Given the specification's repeated references to MS, that is a wise decision on the majority's part.

I do, however, need to discuss the district court's finding (an erroneous one, in my view) that the '514 patent does not contain enough "blaze marks" to " 'link' a therapeutically effective amount of DMF to a dose of 480mg/day." *Biogen*, 2020 WL 3317105, at *10. The district court cites our precedent in *Ariad*, as well as Dr. Greenberg's trial testimony, to justify its application of our "blaze marks" precedent to this case. *Id.* I do not believe our case law required these patentees to include "blaze marks" in the '514 patent, however. And, the district court's reliance on Dr. Greenberg's testimony to conclude that the patentees should have included "blaze marks" only perpetuated its legally erroneous interpretation of our case law. *See* J.A. 1447–49.

It is axiomatic that, to satisfy the written description requirement, a patent specification must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad*, 598 F.3d at 1351 (citations omitted) (alteration in original). This fundamental concept gets tested, however, whenever a ***1351** patent's specification discloses a broad genus and claims a particular species contained within that genus. In cases such as these, our court has crafted a subgenre within our written description jurisprudence that requires patents containing laundry list-type disclosures "to provide sufficient 'blaze marks' to guide a reader through the forest of disclosed possibilities toward the claimed compound." *Novozymes*, 723 F.3d at 1346; *see also In re Ruschig*, 379 F.2d 990, 994–995 (C.C.P.A. 1967) ("It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared ... to be confronted simply by a large number of unmarked trees."). Notably, our "blaze marks" jurisprudence does not apply in *every* case concerning written description; it, instead, provides a useful framework to analyze whether written description has been met in cases involving patents containing laundry list disclosures. *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996) ("In the absence of such blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses.").

On my reading of the '514 patent, the district court erred as a matter of law by requiring Column 18 to contain sufficient "blaze marks" regarding the claimed DMF480 therapeutically effective dose. Method 4 of the '514 patent provides a general discussion of treating neurological diseases, such as MS, with therapeutically effective amounts of DMF compounds. *See* '514 patent, col. 8, ll. 35–53. Column 18 picks up where Method 4 left off by indicating which specific DMF doses the patentees considered therapeutically effective. *See id.*, col. 18, ll. 52–64. Column 18 does this by providing ranges of DMF doses—some large, *see id.* at col. 18, ll. 58–60 ("0.1 g to 1 g per [d]ay"), and some small, *see id.*, col. 18, l. 61 ("240 mg to about 720 mg per day"). Notably, Column 18 contains an express disclosure of the claimed DMF480

dose[4]; this reference also comes in the form of a range. *See id.* at col. 18, l. 62 ("480 mg to about 720 mg per day.").

[4] The majority's decision affirming the district court partially rests on the fact that the '514 patent only mentions the claimed DMF480 dose once. Maj. Op. at 1343. But the majority cites no case law (and I know of none) for the proposition that the written description requirement demands that a patentee recite a claim element repeatedly to pass written description muster. The majority does not, and cannot, deny that the claimed DMF480 dose is expressly disclosed. To the extent the majority's opinion may be read to establish a requirement that a claim element must be disclosed multiple times, I dissent from that holding as well.

I do not believe our "blaze marks" precedent applies to the claimed DMF480 dose because Column 18 does not provide a laundry list disclosure of therapeutically effective doses. Despite providing a varying degree of ranges, Column 18 begins one such range with the *exact* DMF480 dose that is claimed. *See id.* Had the patentees instead listed this range as, e.g., "*100 mg* to about 720 mg per day" and expected a POSA to figure out that a 480 mg per day dose was therapeutically effective, I would agree that "blaze marks" would be necessary to "single out particular trees." *In re Ruschig*, 379 F.2d at 995. But, because the range provided in Column 18 particularly points out the claimed DMF480 dose, I believe the claim satisfies Section 112 and our corresponding written description jurisprudence. The district ***1352** court's application of our "blaze marks" precedent and corresponding reliance on Dr. Greenberg's testimony thus are erroneous as a matter of law for two reasons. First, as discussed above, our "blaze marks" precedent is not applicable to this case because Column 18 lacks a laundry list disclosure. And, second, even if this precedent were to apply here, Column 18 provides a sufficient "blaze mark" by explicitly mentioning the claimed DMF480 dose. How much brighter need a disclosure blaze?

The district court's inability to "link" method 4 and Column 18, moreover, emanates from its original sin of judicially estopping Biogen from distinguishing between therapeutic and clinical effects. With a proper understanding of this distinction, the written description analysis in this case is straightforward: method 4 provides a general description of treating MS using a therapeutically effective DMF dose and column 18 demonstrates the patentees' possession of the claimed DMF480 dose for that purpose.

II.

Because I believe the entire course of the district court's analysis might well change if the court were to adjust the lens through which it considers the evidence and testimony, I would remand for reconsideration of the record with the understanding that the patent is not about clinical efficacy—it is about therapeutic effect—and that the written description and obviousness inquiries are not the same.

All Citations

18 F.4th 1333

379 F.2d 990
United States Court of Customs and Patent Appeals.

Application of Heinrich RUSCHIG, Walter Aumuller, Gerhard Korger, Hans Wagner, Josef Scholz and Alfred Bander.

Patent Appeal No. 8071.
|
June 22, 1967.

Synopsis

Appeal from a decision of the Patent Office Board of Appeals, Serial No. 601,107, affirming rejection of claim of application for new benzene sulfonyl ureas and process for their preparation. The Court of Customs and Patent Appeals, Rich, J., held that claim was properly rejected on ground that compound of the claim was not sufficiently described therein.

Affirmed.

West Headnotes (4)

[1] **Patents** Reconsideration or continued examination

291Patents
291IVPatent Applications and Proceedings
291IV(B)Examination
291k954Reconsideration or continued examination
(Formerly 291k104)

Patent Office had jurisdiction and authority to reopen prosecution and to reject claim of patent on a new ground.

6 Cases that cite this headnote

[2] **Patents** Compositions and compounds

291Patents
291VConstruction and Operation of Patents
291V(C)Particular Fields of Invention
291k1390Compositions and compounds
(Formerly 291k101(9))

Specific claims in a patent application to single compounds require reasonably specific supporting disclosure.

43 Cases that cite this headnote

[3] **Patents** Particular products or processes
Patents Chemicals

291Patents
291IVPatent Applications and Proceedings
291IV(A)In General
291k904Specification
291k907Written Description Requirement
291k907(6)Particular products or processes
(Formerly 291k101(5))
291Patents
291VConstruction and Operation of Patents
291V(C)Particular Fields of Invention
291k1383Chemicals
291k1384In general
(Formerly 291k101(11))

Claim of patent application for new benzene sulfonyl ureas and process for their preparation was properly rejected on ground that compound of the claim was not sufficiently described therein.

23 Cases that cite this headnote

[4] **Patents** In general; utility

291Patents
291XPatents Enumerated
291k2091In general; utility
(Formerly 291k328(2))

US Patent 3,198,706. Cited.

Attorneys and Law Firms

**990 *1552 Eugene O. Retter, Kalamazoo, Mich., John Kekick (Sidney W. Russell, Washington, D.C., of counsel), for appellants.

Joseph Schimmel, Washington, D.C., for the Commissioner of Patents.

Before WORLEY, Chief Judge, RICH, SMITH, and ALMOND, Judges, and WILLIAM H. KIRKPATRICK.*

* Senior District Judge, Eastern District of Pennsylvania, sitting by designation.

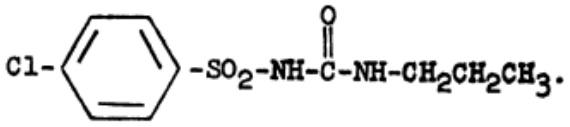
Opinion

**991 RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the rejection of claim 13 of application serial No. 601,107, filed July 31, 1956, for 'New Benzene Sulfonyl Ureas and Process for Their Preparation' Apparently The Upjohn Company has been prosecuting the application.

This case is a sequel to our decision in In re Ruschig, 343 F.2d 965, 52 CCPA 1238, decided April 22, 1965. There we reversed a rejection of twelve claims of this same application based on prior art. The claim on appeal is one of those claims. It reads:

13. N-(p-chlorobenzenesulfonyl) -N-propylurea. That compound is structurally identified as



It is known by the generic name chlorpropamide and is sold under the trademark Diabinese by Chas. Pfizer & Co., Inc., as an oral medication for the control of diabetes mellitus, as more fully explained in our previous opinion, wherein we also had occasion to discuss the claim 13 compound which is again before us. We refer to that opinion for a more complete exposition of the chemical nomenclature and further background.

The sole issue on this appeal is whether claim 13 is supported by the disclosure of appellants' application, a question which had not been raised in this case at the time of the prior appeal. The following events gave rise to the issue.

About a year after the present application was filed, the examiner suggested claim 13 to applicants for purposes of interference with a Pfizer application filed by McLamore, serial No. 660,064 of May 20, 1957, and September 25, 1957, the claim was added. Interference 89,091 was declared and in it McLamore moved to dissolve on the *1553 ground, inter alia, that the claim was not supported in the application at bar. The examiner held the claim was supported and denied the motion. On reconsideration, he adhered to his decision. (The suggestion of the claim and these two decisions on motions are referred to by appellants as three rulings in their favor by the Patent Office, nearly ten years ago, on the present issue.) Later the examiner dissolved the interference on his own motion on the ground claim 13 was unpatentable to the interference parties over prior art. Meanwhile both appellants and McLamore had filed divisional applications claiming methods of treating diabetes and compositions therefor, appellants' application being serial No. 185,865, filed April 9, 1962. It had two sets of claims, 1-4 for tablets and 5-8 for method of treatment. Claims 3 and 7 specified the same compound as that of claim 13. These claims were under rejection by reason of one-year statutory bars which could be overcome only by reliance on the filing date of the present parent application which gave rise to the question whether the application contained support for the claims. In an appeal to the board in application 185,865, by an opinion of March 4, 1965, the board, having gone into the application and interference history, held that claims 3 and 7 in that application did not have support in the present application because the claim 13 compound is not disclosed therein and issued a new rejection under Rule 196(b) on that ground.[1]

[1] The board opinion is reported at 147 USPQ 46. After receiving it, appellants cancelled claims 3 and 7 from application 185,865 and patent No. 3,198,706 was issued thereon, Aug. 3, 1965, to the assignee Farbwerke Hoechst Aktiengesellschaft vormals Meister Lucius & Bruning.

**992 After our decision on the prior appeal, in which we reversed the rejection on prior art, the application was returned to the examiner. Since he knew of the board's action in the other application holding that the disclosure does not support the compound of claim 13, he requested and obtained from the First Assistant Commissioner authorization to reopen the case to reject claim 13 on the

new ground of lack of support, which he did on June 15, 1965, as follows:

In view of the decision of the Board of Appeals of March 4, 1965 in Serial No. 185,865, holding that claims 3 and 7 therein were not supported by the disclosure of the instant case and hence not entitled to the benefit of the date thereof, claim 13 herein which is specific to a compound, the use of which is recited in claims 3 and 7, supra, is rejected as having no specific support in this disclosure for reasons fully detailed in said decision (Appeal No. 283-74), Paper No. 25, at pages 4-7. The compound of claim 13 is not named or identified by formula and it can find support only as choices made between the several variables involved. This is not regarded as adequate support for a specific compound never named or otherwise exemplified in the specification as filed. See In re Fried 1963 C.D. 248 (page 257, first paragraph (50 CCPA 954, 312 F.2d 930, 136 USPQ 729)).

***1554** Appellants then argued this rejection before the examiner who adhered to it and made it final. Reconsideration was requested and given, the examiner adhering to his view. Appellants then took the question to the board where the examiner filed an extensive Answer to their lengthy brief. The board affirmed for very much the same reasons as those stated in its opinion in deciding the same issue in application serial No. 185,865. Thus the question before us has been twice decided adversely to appellants by the Board of Appeals, the same panel hearing both appeals.[2]

[2] Federico and Rosa, Examiners-in-Chief, and Stone, Acting Examiner-in-Chief; opinions by Federco.

In coming here, appellants raise a question in addition to the issue of support which requires preliminary consideration. They say that in this second appeal 'involving the same and already adjudicated Claim, the United States Patent Office was without authority, or lacked jurisdiction, to reopen these proceedings (after the Court's decision) to resurrect a ground of rejection which had already been considered by the Patent Office, this lack of authority being based upon principles of, or akin to, res judicata, estoppel or laches.'

In answer, the solicitor says there is no such issue before us since it was not raised before the board, is raised for the first time in this court, and was not properly raised by any reason of appeal. Appellants counter with the argument that Reason of Appeal 9, reading, 'The Board of Appeals erred in matters of law,' will suffice. They also say that, being a matter of 'jurisdiction over subject matter,' it can be raised at any time.

We pass these ingenious and technical legal arguments since we prefer to say that we have considered the numerous cases relied on by appellants to support their proposition that the Patent Office cannot make this rejection because many years ago an examiner ruled to the contrary and find the point lacking in merit and unsupported by authority. We appreciate the extensive memorandum of law supplied in the appendix to appellants' brief, containing cases pro and con, and note the heavy reliance on what was said in two concurring opinions. We surmise appellants would have to agree that what precedents they have found are not, as a whole, very strong support for their theory. The words of Judge Garrett in In re Ellis, 86 F.2d 412, 24 CCPA 759, which appellants found quoted in In re Becker, 101 F.2d 557, 26 CCPA 922, fairly depict the present ****993** situation, which is not much different from that prevailing in 1936,

There is nothing unusual, certainly, about an examiner changing his viewpoint as to the patentability of claims as the prosecution of a case progresses, and, so long as the rules of Patent Office practice are duly complied with, an applicant has no legal ground for complaint because of such change in view.

***1555** The life of a patent solicitor has always been a hard one.

Appellants insinuate that in our former decision in this case we found all the claims, including claim 13, patentable. Their words are, 'Presently appealed Claim 13 was also indicated as allowable by this Court.' They also say that this application 'was returned by this Court to the Patent Office for issuance * * *.' We did neither of these things. We passed on a rejection on prior art, affirmed by the board, found it in error, and reversed the board decision. Nothing more. Under 35 U.S.C. § 144 the only effect of our decision was to govern further proceedings in the case.

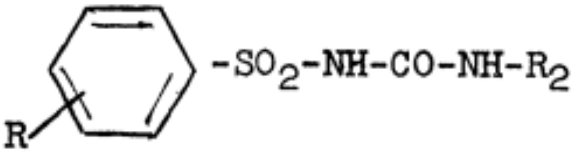
[1] Appellants concede that the Patent Office can reopen a case returned by this court after appeal and reject claims on newly found prior art and attempt to distinguish the present situation on the ground that the rejection now applied is not based on newly found art but on the specification which has been available since the application was filed. Further, they say the very question was adjudged in their favor long ago. We are unable to see that these differences have legal significance. See In re Citron, 326 F.2d 418, 51 CCPA 869. For related views on res judicata as applied to patent prosecution see our recent opinions in In re Herr, 377 F.2d 610, 54 CCPA . We hold the Patent Office had the jurisdiction and the authority to reopen prosecution and to reject claim 13 on a

new ground, to the merits of which rejection we now pass.

We have quoted the examiner's rejection above. His first point was that the compound of claim 13 'was not named or identified by formula' in the specification. Appellants admit this. His next point was that it 'can find support only as choices made between the several variables involved.' These words are the words of Judge Smith in In re Fried, supra, a case in which we found lack of support in general disclosures. Their purport in the factual context of this case is that the reagents for the preparation of chlorpropamide are listed, with many others, in the disclosure and, as the board said, 'If the proper choices of the three variables in the above formula are made, the compound in question is produced,' the formula referred to being that of the family of benzene sulphonylureas in which the variables are R, R(1) and R(2), to be seen in claim 1 reproduced in our former opinion. The board continued its statement, saying, 'but nowhere in the specification is the particular selection indicated.'

[2] It does not seem to be contested that the general disclosure of the application encompasses something like half a million possible compounds.[3] It also discloses a number of specific compounds. Appellants' ***1556** argument is that one skilled in the art would find certain 'guides' in the specification which would lead him to the compound of claim 13 and that the compound is therefore disclosed. Further reliance is placed on our opinion in In re Petering, 301 F.2d 676, 49 CCPA 993, taken in connection with original claim 2, legally deemed a part of the disclosure, which appellants say encompasses only 48 compounds, 'excluding isomers,' ****994** this being in effect one of the 'guides.' Original claim 2 reads:

> 2. Benzenesulphonylureas of the general formula



> wherein R is a member selected from the group consisting of chlorine and bromine and R(2) is a member selected from the group of alkyl-, alkenyl-, cycloalkyl- and cycloalkylalkyl radicals containing 2 to 7 carbon atoms.

Appellants refer to this formula as narrowing the field of selection, so to speak, and say that 'excluding isomers,' there are 'approximately' 48 compounds within the scope of that claim all of which are 'readily determinable by skilled chemists.' What this amounts to is saying that skilled chemists can see that R is either Cl or Br and that R(2) is any one of the radicals above recited. The examiner computes that the number of possible compounds is not approximately 48 but a minimum of 1,010, 'excluding stereoisomerides.' He shows his calculations and we do not find a refutation of them by appellants to justify their contention the number is 48, nor any explanation of how the number 48 is arrived at. The *Petering* case is used for its finding that a particular reference disclosure of a subgeneric class of compounds to the number of only 20, some of which were disclosed by name, was as good as *prior art* disclosure of all 20 as though they had all been named, for the purpose of anticipating an invention, not for the purpose of disclosing it to *support* a claim. As we said in our prior opinion in this case, '*Petering* involved a very special situation * * *.' We do not consider the facts here to be sufficiently similar to make it pertinent. It is not our view that a disclosure such as that to be found in the formula and words of claim 2, above, amounts to a disclosure, sufficient to support a specific claim, of every compound a skilled chemist can see is within the scope of that claim. Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that naming is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required. Surely, given time, a chemist could name (especially with the aid of a computer) ***1557** all of the half million compounds within the scope of the broadest claim, which claim is supported by the broad disclosure. This does not constitute support for each compound individually when separately claimed.

Other 'guides' allegedly leading to chlorpropamide argued by appellants will now be discussed. It is said eleven processes for making the many compounds of the invention are disclosed, five of which employ an

[3] In the companion case of In re McLamore, Cust.Pat.App., 379 F.2d 985, concurrently decided, a PhD. chemist who heads the Pfizer Patent Department has made an affidavit of record in which he shows how he has calculated, on a conservative basis, including sodium and potassium salts, the number of compounds within the broad disclosure of this application to be 1,237,464. We express no view on this mathematical question. The number is very large in any event.

'alkylamine.' This is R(2) in the general formula. But in that formula there is also the variable R which may be hydrogen, chlorine, bromine, methyl, or methoxy and R(1) which may be either chlorine or bromine and, furthermore, R and R(1) may be located anywhere on the benzene ring, that is, ortho, meta, or para to the SO(2) group and adjacent or non-adjacent one another. This makes for more than a few unidentified possibilities not determined by the use of alkylamine alone. To lead to claim 13, R must be hydrogen and R(1) must be chlorine and the alkylamine, R(2), must be propylamine.

Next, it is argued in connection with these processes that in the discussion of Process (1) it is taught that the primary amine could be '*a primary butylamine or another primary alkylamine* or an alkenylamine, cyclo-alkylamine or cycloalkylalkyl-amine containing 2 to 7 or 8 carbon atoms' and that one skilled in the art could *see* that 'if n-butylamine is a reactant, then ethylamine, n-propylamine, etc., are also possible reactants.' We do not see that this guides one *to* the use of n-propylamine. The important words in the quotation from our point of view are 'etc.' and 'possible'. It is an old custom ****995** in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared— or have not yet been made, which is more like the case here— to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

Appellants say next that the 'guide' becomes more crystallized by the recitation of the alkylamines which can be employed in the four or five reactions described as using them. This list contains at least 19 primary amines which the specification says may be used. Appellants emphasize two, n-butylamine, which is elsewhere specifically disclosed as having been used, and n-propylamine. We do not see that listing the latter with the 18 others adds anything to the initial statement that one may use an alkyl amine containing from 2 to 6 carbon atoms. Propylamine is such an amine but one is not led to it in preference to the others merely by listing them all and identifying it, with the others, by name.

Finally appellants refer to two tables listing, respectively, ten and twelve specific compounds, the first being the list of specific compounds whose blood sugar lowering activity is shown in the specification, ***1558** the other, which duplicates the first and adds two compounds, being the specific examples of the specification. There is no N'-n-propyl compound among them. Perhaps one of appellants' best points is that the activity table 'stresses' compounds in which R(2) is a primary alkyl radical, i.e., ethyl, butyl, isobutyl and hexyl. The stress resides in the fact that eight of the ten are such compounds. And one of them, N-(4-chlorobenzenesulphonyl)-N'n-butyl urea, is a homolog of the compound of claim 13. It must be admitted that this is getting close. *If* n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the specification. The trouble is that there is no such disclosure, easy though it is to imagine it. It is equally easy to imagine that the compound of claim 13 might have been named in the specification. Working backward from a knowledge of chlorpropamide, that is by hindsight, it is all very clear what route one would travel through the forest of the specification to arrive at it. But looking at the problem, as we must, from the standpoint of one with no foreknowledge of the specific compound, it is our considered opinion that the board was correct in saying:

Not having been specifically named or mentioned in any manner, one is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made.

[3] Appellants refer to 35 U.S.C. § 112 as the presumed basis for this rejection and emphasize language therein about *enabling* one skilled in the art to make the invention, arguing therefrom that one skilled in the art would be enabled by the specification to make chlorpropamide. We find the argument unpersuasive for two reasons. First, it presumes some motivation for wanting to make the compound in preference to others. While we have no doubt a person so motivated would be enabled by the specification to make it, this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented. We think it does not. Second, we doubt that the rejection is truly based on section 112, at least on the parts relied on by appellants. If based on section 112, it is on the requirement thereof that 'The specification shall contain a written description *of the invention* ****996** * * *.' (Emphasis ours.) We have a specification which describes appellants' invention. The issue here is in no wise a question of its compliance with section 112, it is a question of *fact: Is the compound of claim 13 described therein?* ***1559** Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound? Having considered the specification in the

light that has been shed on it by all the arguments pro and con, we conclude that it does not.

The decision of the board is affirmed.

Affirmed.

All Citations

54 C.C.P.A. 1551, 379 F.2d 990, 154 U.S.P.Q. 118